CONFERENCE COMMITTEE REPORT
DIGEST FOR EHB 1098

Citations Affected: IC 10-13-3-38.5; IC 12-9-5-5; IC 16-18-2; IC 16-27; IC 22-1-5; IC 25-22.5-1-2; IC 25-23-1-27.1; IC 25-26-13-4; IC 25-26-14; IC 25-33-1-9; IC 25-35.6; IC 34-24-1-1; IC 35-43-10.

Synopsis: Prescription drugs and health professions. Establishes a program for the licensing and regulation of personal services agencies. Provides that home health agencies and personal services agencies are approved to provide home health or personal services under certain federal waivers. Provides that home health services include services that are required to be ordered or performed by certain health care professionals. Increases the home health agency license fee. Requires a personal services agency to comply with employee criminal history check requirements. Provides that a home health agency that operates a personal services agency is not required to obtain a license to operate the personal services agency. Makes operating or advertising an unlicensed personal services agency a Class A misdemeanor. Requires a placement agency to provide the consumer and worker with certain information when a home care services worker is placed in the consumer's home. Allows the state department of health to impose a civil penalty against a placement agency for failing to provide the notice. Relocates the definition of "attendant care services". Requires the board of pharmacy to establish procedures to ensure that pharmacies may return expired prescription drugs to drug wholesalers and manufacturers. Specifies information that the board must consider in establishing the procedures. Expands the requirements that must be met by a wholesale drug distributor for eligibility for licensure. Specifies prohibited acts. Allows certain state licensure exams to apply to the psychology reciprocity requirements. Amends several definitions concerning speech-language pathology and audiology. Requires licensure of speech-language pathology aides, associates, and assistants. Amends licensure requirements of speech-language pathologists and audiologists. Requires an audiologist to possess a doctorate degree after January 1, 2007, for an initial license. Allows the professional standards board to issue credentials to certain speech language professionals. Allows certified speech-language pathologists and audiologists who meet certain requirements to be considered to have a National Board of Professional Teaching Standards certification. Requires a referral to administer a test of vestibular function. Amends reciprocity licensure requirements for speech language pathologists and audiologists. Requires licenses to be displayed. Specifies criminal acts related to wholesale drug distribution and legend drugs. Allows the board of pharmacy to establish an electronic pedigree pilot program. Makes conforming changes. **(This conference committee report: (1) adds provisions from SB 206 concerning personal services agencies and home health services; (2) adds provisions from SB 590 concerning wholesale**

drug distribution; (3) allows certain state licensure exams to apply to the psychology reciprocity requirements (HB 1599); and (4) adds provisions from HB 1599 concerning speech and language pathologists.)

Effective: July 1, 2005; January 1, 2006.

Adopted	Rejected

CONFERENCE COMMITTEE REPORT

MR. SPEAKER:

Your Conference Committee appointed to confer with a like committee from the Senate upon Engrossed Senate Amendments to Engrossed House Bill No. 1098 respectfully reports that said two committees have conferred and agreed as follows to wit:

that the House recede from its dissent from all Senate amendments and that the House now concur in all Senate amendments to the bill and that the bill be further amended as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Delete everything after the enacting clause and insert the following:

SECTION 1. IC 10-13-3-38.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 38.5. (a) Under federal P.L.92-544 (86 Stat. 1115), the department may use an individual's fingerprints submitted by the individual for the following purposes:

(1) Determining the individual's suitability for employment with the state, or as an employee of a contractor of the state, in a position:

(A) that has a job description that includes contact with, care of, or supervision over a person less than eighteen (18) years of age;

(B) that has a job description that includes contact with, care of, or supervision over an endangered adult (as defined in IC 12-10-3-2), except the individual is not required to meet the standard for harmed or threatened with harm set forth in IC 12-10-3-2(a)(3);

(C) at a state institution managed by the office of the secretary of family and social services or state department of health;

(D) at the Indiana School for the Deaf established by IC 20-16-2-1;

(E) at the Indiana School for the Blind established by IC 20-15-2-1;

(F) at a juvenile detention facility;

(G) with the gaming commission under IC 4-33-3-16;

(H) with the department of financial institutions under IC 28-11-2-3; or

(I) that has a job description that includes access to or supervision over state financial or personnel data, including state warrants, banking codes, or payroll information pertaining to state employees.

(2) Identification in a request related to an application for a teacher's license submitted to the professional standards board established under IC 20-1-1.4.

(3) Use by the Indiana board of pharmacy in determining the individual's suitability for a position or employment with a wholesale drug distributor, as specified in IC 25-26-14-16(b), IC 25-26-14-16.5(b), IC 25-26-14-17.8(c), and IC 25-26-14-20.

An applicant shall submit the fingerprints in an appropriate format or on forms provided for the employment or license application. The department shall charge each applicant the fee established under section 28 of this chapter and by federal authorities to defray the costs associated with a search for and classification of the applicant's fingerprints. The department may forward fingerprints submitted by an applicant to the Federal Bureau of Investigation or any other agency for processing. The state personnel department or the agency to which the applicant is applying for employment or a license may receive the results of all fingerprint investigations.

(b) An applicant who is an employee of the state may not be charged under subsection (a).

(c) Subsection (a)(1) does not apply to an employee of a contractor of the state if the contract involves the construction or repair of a capital project or other public works project of the state.

SECTION 2. IC 12-9-5-5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 5. Notwithstanding any other law:**

(1) home health agencies licensed under IC 16-27-1 are approved to provide home health services; and

(2) personal services agencies licensed under IC 16-27-4 are approved to provide personal services;

under any federal waiver granted to the state under 42 U.S.C. 1315 or 42 U.S.C. 1396n.

SECTION 3. IC 16-18-2-28.5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 28.5. **(a)** "Attendant care services", for purposes of IC 16-27-1 ~~has the meaning set forth in IC 16-27-1-0.5.~~ **and IC 16-27-4, means services:**

(1) that could be performed by an impaired individual for whom the services are provided if the individual were not impaired; and

(2) that enable the impaired individual:

(A) to live in the individual's home and community rather than in an institution; and

(B) to carry out functions of daily living, self-care, and mobility.

(b) The term includes the following:

(1) Assistance in getting in and out of beds, wheelchairs, and motor vehicles.

(2) Assistance with routine bodily functions, including:

(A) bathing and personal hygiene;

(B) using the toilet;

(C) dressing and grooming; and

(D) feeding, including preparation and cleanup.

(3) The provision of assistance:

(A) through providing reminders or cues to take medication, the opening of preset medication containers, and providing assistance in the handling or ingesting of noncontrolled substance medications, including eye drops, herbs, supplements, and over-the-counter medications; and

(B) to an individual who is unable to accomplish the task due to an impairment and who is:

(i) competent and has directed the services; or

(ii) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.

SECTION 4. IC 16-18-2-56.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 56.3. "Client", for purposes of IC 16-27-4, has the meaning set forth in IC 16-27-4-1.**

SECTION 5. IC 16-18-2-162 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 162. (a) "Health care professional", for purposes of IC 16-27-1 **and IC 16-27-4,** has the meaning set forth in IC 16-27-1-1.

(b) "Health care professional", for purposes of IC 16-27-2, has the meaning set forth in IC 16-27-2-1.

SECTION 6. IC 16-18-2-266.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 266.5. "Parent personal services agency", for purposes of IC 16-27-4, has the meaning set forth in IC 16-27-4-2.**

SECTION 7. IC 16-18-2-277.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 277.6. "Personal representative", for purposes of IC 16-27-4, has the meaning set forth in IC 16-27-4-3.**

SECTION 8. IC 16-18-2-277.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 277.7. "Personal services", for purposes of IC 16-27-2 and IC 16-27-4, has the meaning set forth in IC 16-27-4-4.**

SECTION 9. IC 16-18-2-277.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 277.8. "Personal services agency", for purposes of IC 16-27-4, has the meaning set forth in IC 16-27-4-5.**

SECTION 10. IC 16-27-1-5 IS AMENDED TO READ AS

FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 5. (a) As used in this chapter, "home health services" means services that: ~~are:~~

(1) **are** provided to a patient by:

(A) a home health agency; or

(B) another person under an arrangement with a home health agency;

in the temporary or permanent residence of the patient; and

(2) **either, are required by law to be:**

(A) ordered by a licensed physician, a licensed dentist, a licensed chiropractor, a licensed podiatrist, or a licensed optometrist **for the service to be performed; or**

(B) performed only by a health care professional.

(b) The term includes the following:

(1) Nursing treatment and procedures.

(2) Physical therapy.

(3) Occupational therapy.

(4) Speech therapy.

(5) Medical social services.

(6) Home health aide services.

(7) Other therapeutic services.

(c) The term does not apply to the following:

(1) Services provided by a physician licensed under IC 25-22.5.

(2) Incidental services provided by a licensed health facility to patients of the licensed health facility.

(3) Services provided by employers or membership organizations using health care professionals for their employees, members, and families of the employees or members if the health or home care services are not the predominant purpose of the employer or a membership organization's business.

(4) Nonmedical nursing care given in accordance with the tenets and practice of a recognized church or religious denomination to a patient who depends upon healing by prayer and spiritual means alone in accordance with the tenets and practices of the patient's church or religious denomination.

(5) Services that are allowed to be performed by an attendant under IC 16-27-1-10.

(6) Authorized services provided by a personal services attendant under IC 12-10-17.

SECTION 11. IC 16-27-1-7 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 7. The state department shall adopt rules under IC 4-22-2 to do the following:

(1) Protect the health, safety, and welfare of patients.

(2) Govern the qualifications of applicants for licenses.

(3) Govern the operating policies, supervision, and maintenance of service records of home health agencies.

(4) Govern the procedure for issuing, renewing, denying, or revoking an annual license to a home health agency, including the following:

(A) The form and content of the license.

(B) The collection of an annual license fee of not more than two hundred **fifty** dollars ~~($200)~~ **($250)** that the state department may

waive.

(5) Exempt persons who do not provide home health services under this chapter.

SECTION 12. IC 16-27-2-2.2 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 2.2. As used in this chapter, "services" includes:

(1) home health services (as defined in IC 16-27-1-5); ~~and~~

(2) any services such as homemaker, companion, sitter, or handyman services provided by a home health agency in the temporary or permanent residence of a patient or client of the home health agency; **and**

(3) personal services.

SECTION 13. IC 16-27-2-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 3. (a) A person may not operate a home health agency **or a personal services agency** if the person has been convicted of any of the following:

(1) Rape (IC 35-42-4-1).

(2) Criminal deviate conduct (IC 35-42-4-2).

(3) Exploitation of an endangered adult (IC 35-46-1-12).

(4) Failure to report battery, neglect, or exploitation of an endangered adult (IC 35-46-1-13).

(5) Theft (IC 35-43-4), if the person's conviction for theft occurred less than ten (10) years before the date of submission by the person of an application for licensure as a home health agency under IC 16-27-1 **or as a personal services agency under IC 16-27-4.**

(b) A person who knowingly or intentionally violates this section commits a Class A misdemeanor.

SECTION 14. IC 16-27-2-4 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. (a) A person who operates a home health agency **under IC 16-27-1 or a personal services agency under IC 16-27-4** shall apply, not more than three (3) business days after the date that an employee begins to provide services in a patient's temporary or permanent residence, for a copy of the employee's limited criminal history from the Indiana central repository for criminal history information under IC 10-13-3.

(b) A home health agency **or personal services agency** may not employ a person to provide services in a patient's or client's temporary or permanent residence for more than three (3) business days without applying for that person's limited criminal history as required by subsection (a).

SECTION 15. IC 16-27-2-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 5. (a) Except as provided in subsection (b), a person who operates a home health agency **under IC 16-27-1 or a personal services agency under IC 16-27-4** may not employ a person to provide services in a patient's or client's temporary or permanent residence if that person's limited criminal history indicates that the person has been convicted of any of the following:

(1) Rape (IC 35-42-4-1).

(2) Criminal deviate conduct (IC 35-42-4-2).

(3) Exploitation of an endangered adult (IC 35-46-1-12).

(4) Failure to report battery, neglect, or exploitation of an endangered adult (IC 35-46-1-13).

(5) Theft (IC 35-43-4), if the conviction for theft occurred less than ten (10) years before the person's employment application date.

(b) A home health agency **or personal services agency** may not employ a person to provide services in a patient's or client's temporary or permanent residence for more than twenty-one (21) calendar days without receipt of that person's limited criminal history required by section 4 of this chapter, unless the Indiana central repository for criminal history information under IC 10-13-3 is solely responsible for failing to provide the person's limited criminal history to the home health agency **or personal services agency** within the time required under this subsection.

SECTION 16. IC 16-27-2-6 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. (a) A person who operates a home health agency **or a personal services agency under IC 16-27-4** is responsible for the payment of fees under IC 10-13-3-30 and other fees required under section 4 of this chapter.

(b) A home health agency **or personal services agency** may require a person who applies to the home health agency **or personal services agency** for employment to provide services in a patient's or client's temporary or permanent residence:

(1) to pay the cost of fees described in subsection (a) to the home health agency **or personal services agency** at the time the person submits an application for employment; or

(2) to reimburse the home health agency **or personal services agency** for the cost of fees described in subsection (a).

SECTION 17. IC 16-27-2-7 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 7. A person who:

(1) operates a home health agency **or personal services agency;** and

(2) violates section 4 or 5 of this chapter;

commits a Class A infraction.

SECTION 18. IC 16-27-4 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]:

Chapter 4. Licensure of Personal Services Agencies

Sec. 1. As used in this chapter, "client" means an individual who has been accepted to receive personal services from a personal services agency.

Sec. 2. As used in this chapter, "parent personal services agency" means the personal services agency that develops and maintains administrative and fiscal control over a branch office.

Sec. 3. As used in this chapter, "personal representative" means a person who has legal authority to act on behalf of the client with regard to the action to be taken.

Sec. 4. (a) As used in this chapter, "personal services" means:

(1) attendant care services;

(2) homemaker services that assist with or perform household tasks, including housekeeping, shopping, laundry, meal planning and preparation, and cleaning; and

(3) companion services that provide fellowship, care, and protection for a client, including transportation, letter writing, mail reading, and escort services;

that are provided to a client at the client's residence.

(b) The term does not apply to the following:

(1) Incidental services provided by a licensed health facility to patients of the licensed health facility.

(2) Services provided by employers or membership organizations for their employees, members, and families of the employees or members if the services are not the predominant purpose of the employer or the membership organization's business.

(3) Services that are allowed to be performed by a personal services attendant under IC 12-10-17.

(4) Services that require the order of a health care professional for the services to be lawfully performed in Indiana.

(5) Assisted living Medicaid waiver services.

(6) Services that are performed by a facility described in IC 12-10-15.

Sec. 5. (a) As used in this chapter, "personal services agency" means a person that provides or offers to provide a personal service for compensation, whether through the agency's own employees or by arrangement with another person.

(b) The term does not include the following:

(1) An individual who provides personal services only to the individual's family or to not more than three (3) individuals per residence and not more than a total of seven (7) individuals concurrently. As used in this subdivision, "family" means the individual's spouse, child, parent, parent-in-law, grandparent, grandchild, brother, brother-in-law, sister, sister-in-law, aunt, aunt-in-law, uncle, uncle-in-law, niece, and nephew.

(2) A local health department as described in IC 16-20 or IC 16-22-8.

(3) A person that:

(A) is approved by the division of disability, aging, and rehabilitative services to provide supported living services or supported living support to individuals with developmental disabilities;

(B) is subject to rules adopted under IC 12-11-2.1; and

(C) serves only individuals with developmental disabilities who are in a placement authorized under IC 12-11-2.1-4.

Sec. 6. (a) To operate a personal services agency, a person must obtain a license from the state health commissioner. A personal services agency may not be opened, operated, managed, or maintained or conduct business without a license from the state department. Each parent personal services agency must obtain a separate license.

(b) A parent personal services agency may maintain branch offices that operate under the license of the parent personal services agency. Each branch office must be:

(1) at a location or site from which the personal services agency

provides services;

(2) owned and controlled by the parent personal services agency; and

(3) located within a radius of one hundred twenty (120) miles of the parent personal services agency.

(c) A license is required for any personal services agency providing services in Indiana. An out-of-state personal services agency must be authorized by the secretary of state to conduct business in Indiana and have a branch office in Indiana.

(d) Application for a license to operate a personal services agency must be made on a form provided by the state department and must be accompanied by the payment of a fee of two hundred fifty dollars ($250). The application may not require any information except as required under this chapter.

(e) After receiving a completed application that demonstrates prima facie compliance with the requirements of this chapter and the payment of the fee required by subsection (d), the state department shall issue a license to the applicant to operate a personal services agency. The state department may conduct an onsite inspection in conjunction with the issuance of an initial license or the renewal of a license.

(f) In the state department's consideration of:

(1) an application for licensure;

(2) an application for renewal of licensure;

(3) a complaint alleging noncompliance with the requirements of this chapter; or

(4) an investigation conducted under section 7(a) of this chapter;

the state department's onsite inspections in conjunction with those actions are limited to determining the personal service agency's compliance with the requirements of this chapter or permitting or aiding an illegal act in a personal services agency.

(g) Subject to subsection (e), when conducting an onsite inspection, the state department must receive all documents necessary to determine the personal service agency's compliance with the requirements of this chapter. A personal services agency must produce documents requested by the state department surveyor not less than twenty-four (24) hours after the documents have been requested.

(h) A license expires one (1) year after the date of issuance of the license under subsection (e). However, the state department may issue an initial license for a period of less than one (1) year to stagger the expiration dates. The licensee shall notify the state department in writing at least thirty (30) days before closing or selling the personal services agency.

(i) A personal services agency license may not be transferred or assigned. Upon sale, assignment, lease, or other transfer, including transfers that qualify as a change in ownership, the new owner or person in interest must obtain a license from the state department under this chapter before maintaining, operating, or conducting the personal services agency.

(j) A home health agency licensed under IC 16-27-1 that operates a personal services agency within the home health agency is subject to the requirements of this chapter. The requirements under IC 16-27-1 do not apply to a home health agency's personal services agency. The requirements under this chapter do not apply to a home health agency's operations. A home health agency that is licensed under IC 16-27-1 is not required to obtain a license under this chapter.

(k) If a person who is licensed to operate a personal services agency is also licensed to operate a home health agency under IC 16-27-1, an onsite inspection for renewal of the person's personal services agency license must, to the extent feasible, be conducted at the same time as an onsite inspection for the home health agency license.

Sec. 7. (a) The state department shall investigate a report of an unlicensed personal services agency operation and report its findings to the attorney general.

(b) The attorney general may do the following:

(1) Seek an injunction in the circuit or superior court of the county in which the unlicensed home health agency is located.

(2) Prosecute violations under section 23 of this chapter.

Sec. 8. (a) If a personal services agency is aware that the client's medical or health condition has become unstable or unpredictable, the personal services agency shall notify the client, the client's personal representative, a family member, other relative of the client, or other person identified by the client of the need for a referral for medical or health services. The notification may be given in writing or orally and must be documented in the client's record with the personal services agency.

(b) The personal services agency may continue to provide personal services for a client with an unstable or unpredictable medical or health condition but may not manage or represent itself as able to manage the client's medical or health condition.

Sec. 9. (a) A personal services agency shall employ an individual to act as the personal services agency's manager. The manager is responsible for the organization and daily operation of the personal services agency.

(b) The manager may designate in writing one (1) or more individuals to act on behalf of or to perform any or all the responsibilities of the personal services agency's manager under this chapter.

Sec. 10. The personal services agency's manager or the manager's designee shall prepare a service plan for a client before providing personal services for the client. A permanent change to the service plan requires a written change to the service plan. The service plan must:

(1) be in writing, dated, and signed by the individual who prepared it;

(2) list the types and schedule of services to be provided; and

(3) state that the services to be provided to the client are subject to the client's right to temporarily suspend,

permanently terminate, temporarily add, or permanently add the provision of any service.

All permanent changes require a change in the written service plan. The service plan must be signed and dated by the client not later than fourteen (14) days after services begin for the client and not later than fourteen (14) days after any permanent change to the service plan.

Sec. 11. The personal services agency's manager or the manager's designee shall conduct a client satisfaction review with the client every seventy-six (76) to one hundred four (104) days to discuss the services being provided and to determine if any change in the plan of services should occur. The review with the client may be in person or by telephone. This client satisfaction review must:

(1) be put in writing; and

(2) be signed and dated by the individual conducting the review.

Sec. 12. The personal services agency shall provide the client or the client's personal representative with the personal services agency's written statement of client rights not more than seven (7) days after providing services to the client. The statement of client rights must include the following information:

(1) The client has the right to have the client's property treated with respect.

(2) The client has the right to temporarily suspend, permanently terminate, temporarily add, or permanently add services in the service plan.

(3) The client has the right to file grievances regarding services furnished or regarding the lack of respect for property by the personal services agency and is not subject to discrimination or reprisal for filing a grievance.

(4) The client has the right to be free from verbal, physical, and psychological abuse and to be treated with dignity.

(5) A statement that it is not within the scope of the personal services agency's license to manage the medical and health conditions of the client if a condition becomes unstable or unpredictable.

(6) The charges for services provided by the personal services agency.

(7) The personal services agency's policy for notifying the client of any increase in the cost of services.

(8) The hours the personal services agency's office is open for business.

(9) That on request the personal services agency will make available to the client a written list of the names and addresses of all persons having at least a five percent (5%) ownership or controlling interest in the personal services agency.

(10) The procedures for contacting the personal services agency's manager, or the manager's designee, while the personal services agency's office is open or closed.

(11) The procedure and telephone number to call to file a complaint with the personal services agency.

(12) That the state department does not inspect personal service agencies as part of the licensing process but does investigate complaints concerning personal service agencies.

(13) The procedure and telephone number to call to file a complaint with the state department along with the business hours of the state department.

Sec. 13. A personal services agency shall investigate a complaint made by a client, the client's family, or the client's personal representative regarding:

(1) service that is or fails to be furnished; and

(2) lack of respect for the client's property by anyone furnishing services on behalf of the personal services agency.

The personal services agency shall document the complaint and the resolution of the complaint.

Sec. 14. The personal services agency's manager or the manager's designee shall be available to respond to client telephone calls twenty-four (24) hours a day.

Sec. 15. An employee or agent of a personal services agency who will have direct client contact must complete a tuberculosis test in the same manner as required by the state department for licensed home health agency employees and agents.

Sec. 16. (a) The competency of an employee or agent of a personal services agency who will perform attendant care services at the client's residence must be evaluated by the agency or the agency's designee for each attendant care services task that the personal services agency chooses to have that employee or agent perform. The agency has the sole discretion to determine if an employee or agent is competent to perform an attendant care services task.

(b) After an evaluation, an employee or agent shall be trained in the attendant care services tasks the personal services agency believes require improvement. The employee or agent shall be reevaluated following any training. The evaluation of the employee or agent and determination by the agency that the employee or agent is competent to perform the attendant care services task must occur before the employee or agent performs that task for a client without direct agency supervision.

(c) The content of the evaluation and training conducted under this section, including the date and the signature of the person conducting the evaluation and training, must be documented for each employee or agent who performs personal services.

Sec. 17. (a) Disclosure of ownership and management information must be made to the state department:

(1) at the time of the personal services agency's request for licensure;

(2) during each survey of the personal services agency; and

(3) when there is a change in the management or in an ownership interest of more than five percent (5%) of the personal services agency.

(b) The disclosure under subsection (a) must include the following:

(1) The name and address of all persons having at least five

percent (5%) ownership or controlling interest in the personal services agency.

(2) The name and address of each person who is an officer, a director, a managing agent, or a managing employee of the personal services agency.

(3) The name and address of the person responsible for the management of the personal services agency.

(4) The name and address of the chief executive officer and the chairperson (or holder of the equivalent position) of the governing body that is responsible for the person identified under subdivision (3).

(c) The determination of an ownership interest and the percentage of an ownership interest under this chapter must be determined under 45 CFR 420.201 and 45 CFR 420.202, as in effect on July 1, 2005.

Sec. 18. A personal services agency shall document evidence of compliance with the requirements of this chapter and document services provided to clients. The documentation or copies of the documentation must be maintained or be electronically accessible at a personal services agency's office in Indiana for not less than seven (7) years.

Sec. 19. (a) The state health commissioner may take one (1) or more of the following actions on any ground listed in subsection (b):

(1) Issue a probationary license.

(2) Conduct a resurvey.

(3) Deny renewal of a license.

(4) Revoke a license.

(5) Impose a civil penalty in an amount not to exceed one thousand dollars ($1,000).

(b) The state health commissioner may take action under subsection (a) on any of the following grounds:

(1) Violation of a provision of this chapter or a rule adopted under this chapter.

(2) Permitting, aiding, or abetting the commission of an illegal act in a personal services agency.

(c) IC 4-21.5 applies to an action under this section.

Sec. 20. (a) The state department shall adopt rules under IC 4-22-2 to govern the procedure for the following:

(1) Issuing, renewing, denying, or revoking a personal services agency license.

(2) Investigating a complaint against a personal services agency that alleges a violation of this chapter.

(3) Collecting fees required under this chapter.

(b) The state department may not add to the substantive or procedural requirements in this chapter.

Sec. 21. A licensee or an applicant for a license aggrieved by an action under this chapter may request a review under IC 4-21.5.

Sec. 22. (a) In response to a request for review of an order referred to in subsection (c), the executive board shall appoint an appeals panel that consists of three (3) members as follows:

(1) One (1) member of the executive board.

(2) One (1) attorney admitted to the practice of law in Indiana.

(3) One (1) individual with qualifications determined by the executive board.

(b) An employee of the state department may not be a member of the panel.

(c) The panel shall conduct proceedings for review of an order issued by an administrative law judge under this chapter. The panel is the ultimate authority under IC 4-21.5.

Sec. 23. A person who knowingly or intentionally:

(1) operates a personal services agency; or

(2) advertises the operation of a personal services agency;

that is not licensed under this chapter commits a Class A misdemeanor.

SECTION 19. IC 22-1-5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]:

Chapter 5. Home Care Consumers and Worker Protection

Sec. 1. As used in this chapter, "attendant care services" has the meaning set forth in IC 16-18-2-28.5.

Sec. 2. As used in this chapter, "companion type services" refers to services described in IC 12-10-17-2(2).

Sec. 3. As used in this chapter, "consumer" means an individual who:

(1) receives home care services given by a home care services worker in the individual's residence; or

(2) pays for and directs the home care services for another individual.

Sec. 4. As used in this chapter, "consumer notice" means the notice described in section 14 of this chapter.

Sec. 5. As used in this chapter, "department" refers to the department of labor created under IC 22-1-1-1.

Sec. 6. As used in this chapter, "home care services" means skilled and unskilled services provided to an individual at the individual's residence to enable the individual to remain in the residence safely and comfortably. The provision of at least two (2) of the following is included in home care services:

(1) Nursing.

(2) Therapy.

(3) Attendant care.

(4) Companion type services.

(5) Homemaker services.

Sec. 7. As used in this chapter, "home care services worker" means an individual performing home care services for compensation.

Sec. 8. As used in this chapter, "homemaker services" means assistance with or performing household tasks that include housekeeping, shopping, laundry, meal planning and preparation, handyman services, and seasonal chores.

Sec. 9. As used in this chapter, "placement agency" means a person engaged in the business of securing home care services

employment for an individual or securing a home care services worker for a consumer. The term:

(1) includes an employment agency, a nurse registry, and an entity that places a home care services worker for compensation by a consumer in the consumer's residence to provide home care services; and

(2) does not include a worker who solely and personally provides home care services to another individual at the residence of that individual.

Sec. 10. As used in this chapter, "skilled services" means services provided by a:

(1) registered nurse (as defined in IC 25-23-1-1.1(a));

(2) licensed practical nurse (as defined in IC 25-23-1-1.2); or

(3) health care professional listed in IC 16-27-1-1.

Sec. 11. As used in this chapter, "worker notice" means the statement described in section 17 of this chapter.

Sec. 12. This chapter applies to a placement agency, but does not apply to a:

(1) hospital (as defined in IC 16-18-2-179);

(2) health facility (as defined in IC 16-18-2-167(a)); or

(3) home health agency (as defined in IC 16-18-2-173).

Sec. 13. (a) A placement agency:

(1) must provide a consumer with a consumer notice each time a home care services worker is placed in the home of the consumer; and

(2) is not required to provide a consumer notice when a new or different home care services worker is substituting for the regular home care services worker placed with the consumer.

(b) Before a placement agency places a home care services worker with a consumer, the home care services worker must provide the placement agency with a copy of the individual's limited criminal history from the central repository for criminal history information under IC 10-13-3. The home care services worker is responsible for the fees required under IC 10-13-3-30 and must annually obtain an updated limited criminal history. A copy of the home care services worker's limited criminal history must be made available to the consumer.

Sec. 14. A consumer notice must include the following:

(1) The duties, responsibilities, and obligations of the placement agency to the:

(A) home care services worker; and

(B) consumer.

(2) A statement identifying the placement agency as:

(A) an employer;

(B) a joint employer;

(C) a leasing employer; or

(D) not an employer.

(3) A statement that notwithstanding the employment status of the placement agency, the consumer:

(A) may be considered an employer under state and federal employment laws; and

(B) may be responsible for:

(i) payment of local, state, or federal employment taxes;

(ii) payment for Social Security and Medicare contributions;

(iii) ensuring payment of at least the minimum wage;

(iv) overtime payment;

(v) unemployment contributions under IC 22-4-11; or

(vi) worker's compensation insurance as required by IC 22-3-2-5 and IC 22-3-7-34;

of the home care services worker.

(4) The appropriate telephone number, address, and electronic mail address of the department for inquiries regarding the contents of the notice.

The department shall determine the content and format of the consumer notice.

Sec. 15. The failure of a placement agency to provide a consumer notice to the consumer at the time a home care services worker is placed in the consumer's home does not relieve a consumer from the duties or obligations as an employer. If a placement agency fails to provide a consumer notice and the consumer is liable for payment of wages, taxes, worker's compensation insurance premiums, or unemployment compensation employer contributions, the consumer has a right of indemnification against the placement agency, which includes the actual amounts paid to or on behalf of the home care services worker as well as the consumer's attorney's fees and costs.

Sec. 16. A placement agency that will not be the actual employer of the home care services worker shall provide a worker notice as set forth in section 17 of this chapter to a home care services worker who is placed with a consumer. The worker notice must:

(1) be provided to the home care services worker upon placement in the consumer's home; and

(2) specify the home care services worker's legal relationship with the placement agency and the consumer.

Sec. 17. The worker notice referred to in section 16 of this chapter must contain the following:

(1) The duties, responsibilities, and obligations of the placement agency, the consumer, and the home care services worker if the home care services worker is determined to be an independent contractor, including:

(A) a statement of the party responsible for the payment of the home care services worker's wages, taxes, Social Security and Medicare contributions, unemployment contributions, and worker's compensation insurance premiums; and

(B) a statement identifying the party responsible for the home care services worker's hiring, firing, discipline, day to day supervision, assignment of duties, and provision of equipment or materials for use by the home care services worker.

(2) The telephone number, address, and electronic mail address of the department for inquiries regarding the contents of the

notice.

The department shall determine the content and format of the consumer notice.

Sec. 18. The department may at any time and upon receiving a complaint from an interested person investigate an alleged violation of this chapter by a placement agency.

Sec. 19. The department may impose a civil penalty not to exceed one thousand dollars ($1,000) against a placement agency that fails to provide a worker notice or a consumer notice at the times required under section 13 or 16 of this chapter. The civil penalty may be assessed by the department and, if necessary, shall be recovered by the prosecuting attorney of the county in which the violation has occurred or by the attorney general, as provided in IC 22-1-1-18.

SECTION 20. IC 25-22.5-1-2 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 2. (a) This article, as it relates to the unlawful or unauthorized practice of medicine or osteopathic medicine, does not apply to any of the following:

(1) A student in training in a medical school approved by the board, or while performing duties as an intern or a resident in a hospital under the supervision of the hospital's staff or in a program approved by the medical school.

(2) A person who renders service in case of emergency where no fee or other consideration is contemplated, charged, or received.

(3) A paramedic (as defined in IC 16-18-2-266), an emergency medical technician-basic advanced (as defined in IC 16-18-2-112.5), an emergency medical technician-intermediate (as defined in IC 16-18-2-112.7), an emergency medical technician (as defined in IC 16-18-2-112), or a person with equivalent certification from another state who renders advanced life support (as defined in IC 16-18-2-7) or basic life support (as defined in IC 16-18-2-33.5):

(A) during a disaster emergency declared by the governor under IC 10-14-3-12 in response to an act that the governor in good faith believes to be an act of terrorism (as defined in IC 35-41-1-26.5); and

(B) in accordance with the rules adopted by the Indiana emergency medical services commission or the disaster emergency declaration of the governor.

(4) Commissioned medical officers or medical service officers of the armed forces of the United States, the United States Public Health Service, and medical officers of the United States Department of Veterans Affairs in the discharge of their official duties in Indiana.

(5) An individual who is not a licensee who resides in another state or country and is authorized to practice medicine or osteopathic medicine there, who is called in for consultation by an individual licensed to practice medicine or osteopathic medicine in Indiana.

(6) A person administering a domestic or family remedy to a member of the person's family.

(7) A member of a church practicing the religious tenets of the

church if the member does not make a medical diagnosis, prescribe or administer drugs or medicines, perform surgical or physical operations, or assume the title of or profess to be a physician.

(8) A school corporation and a school employee who acts under IC 34-30-14 (or IC 34-4-16.5-3.5 before its repeal).

(9) A chiropractor practicing the chiropractor's profession under IC 25-10 or to an employee of a chiropractor acting under the direction and supervision of the chiropractor under IC 25-10-1-13.

(10) A dental hygienist practicing the dental hygienist's profession under IC 25-13.

(11) A dentist practicing the dentist's profession under IC 25-14.

(12) A hearing aid dealer practicing the hearing aid dealer's profession under IC 25-20.

(13) A nurse practicing the nurse's profession under IC 25-23. However, a registered nurse may administer anesthesia if the registered nurse acts under the direction of and in the immediate presence of a physician and holds a certificate of completion of a course in anesthesia approved by the American Association of Nurse Anesthetists or a course approved by the board.

(14) An optometrist practicing the optometrist's profession under IC 25-24.

(15) A pharmacist practicing the pharmacist's profession under IC 25-26.

(16) A physical therapist practicing the physical therapist's profession under IC 25-27.

(17) A podiatrist practicing the podiatrist's profession under IC 25-29.

(18) A psychologist practicing the psychologist's profession under IC 25-33.

(19) A speech-language pathologist or audiologist practicing the pathologist's or audiologist's profession under IC 25-35.6.

(20) An employee of a physician or group of physicians who performs an act, a duty, or a function that is customarily within the specific area of practice of the employing physician or group of physicians, if the act, duty, or function is performed under the direction and supervision of the employing physician or a physician of the employing group within whose area of practice the act, duty, or function falls. An employee may not make a diagnosis or prescribe a treatment and must report the results of an examination of a patient conducted by the employee to the employing physician or the physician of the employing group under whose supervision the employee is working. An employee may not administer medication without the specific order of the employing physician or a physician of the employing group. Unless an employee is licensed or registered to independently practice in a profession described in subdivisions (9) through (18), nothing in this subsection grants the employee independent practitioner status or the authority to perform patient services in an independent practice in a profession.

(21) A hospital licensed under IC 16-21 or IC 12-25.

(22) A health care organization whose members, shareholders, or

partners are individuals, partnerships, corporations, facilities, or institutions licensed or legally authorized by this state to provide health care or professional services as:

(A) a physician;

(B) a psychiatric hospital;

(C) a hospital;

(D) a health maintenance organization or limited service health maintenance organization;

(E) a health facility;

(F) a dentist;

(G) a registered or licensed practical nurse;

(H) a midwife;

(I) an optometrist;

(J) a podiatrist;

(K) a chiropractor;

(L) a physical therapist; or

(M) a psychologist.

(23) A physician assistant practicing the physician assistant's profession under IC 25-27.5.

(24) A physician providing medical treatment under IC 25-22.5-1-2.1.

(25) An attendant who provides **attendant** care services (as defined in ~~IC 16-27-1-0.5.~~ **IC 16-18-2-28.5).**

(26) A personal services attendant providing authorized attendant care services under IC 12-10-17.

(b) A person described in subsection (a)(9) through (a)(18) is not excluded from the application of this article if:

(1) the person performs an act that an Indiana statute does not authorize the person to perform; and

(2) the act qualifies in whole or in part as the practice of medicine or osteopathic medicine.

(c) An employment or other contractual relationship between an entity described in subsection (a)(21) through (a)(22) and a licensed physician does not constitute the unlawful practice of medicine under this article if the entity does not direct or control independent medical acts, decisions, or judgment of the licensed physician. However, if the direction or control is done by the entity under IC 34-30-15 (or IC 34-4-12.6 before its repeal), the entity is excluded from the application of this article as it relates to the unlawful practice of medicine or osteopathic medicine.

(d) This subsection does not apply to a prescription or drug order for a legend drug that is filled or refilled in a pharmacy owned or operated by a hospital licensed under IC 16-21. A physician licensed in Indiana who permits or authorizes a person to fill or refill a prescription or drug order for a legend drug except as authorized in IC 16-42-19-11 through IC 16-42-19-19 is subject to disciplinary action under IC 25-1-9. A person who violates this subsection commits the unlawful practice of medicine under this chapter.

(e) A person described in subsection (a)(8) shall not be authorized to dispense contraceptives or birth control devices.

SECTION 21. IC 25-23-1-27.1 IS AMENDED TO READ AS

FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 27.1. (a) As used in this section, "licensed health professional" means:

(1) a registered nurse;

(2) a licensed practical nurse;

(3) a physician with an unlimited license to practice medicine or osteopathic medicine;

(4) a licensed dentist;

(5) a licensed chiropractor;

(6) a licensed optometrist;

(7) a licensed pharmacist;

(8) a licensed physical therapist;

(9) a licensed psychologist;

(10) a licensed podiatrist; or

(11) a licensed speech-language pathologist or audiologist.

(b) This chapter does not prohibit:

(1) furnishing nursing assistance in an emergency;

(2) the practice of nursing by any student enrolled in a board approved nursing education program where such practice is incidental to the student's program of study;

(3) the practice of any nurse who is employed by the government of the United States or any of its bureaus, divisions, or agencies while in the discharge of the nurse's official duties;

(4) the gratuitous care of sick, injured, or infirm individuals by friends or the family of that individual;

(5) the care of the sick, injured, or infirm in the home for compensation if the person assists only:

(A) with personal care;

(B) in the administration of a domestic or family remedy; or

(C) in the administration of a remedy that is ordered by a licensed health professional and that is within the scope of practice of the licensed health professional under Indiana law;

(6) performance of tasks by persons who provide health care services which are delegated or ordered by licensed health professionals, if the delegated or ordered tasks do not exceed the scope of practice of the licensed health professionals under Indiana law;

(7) a physician with an unlimited license to practice medicine or osteopathic medicine in Indiana, a licensed dentist, chiropractor, dental hygienist, optometrist, pharmacist, physical therapist, podiatrist, psychologist, speech-language pathologist, or audiologist from practicing the person's profession;

(8) a school corporation or school employee from acting under IC 34-30-14;

(9) a personal services attendant from providing authorized attendant care services under IC 12-10-17; or

(10) an attendant who provides attendant care services (as defined ~~by IC 16-27-1-0.5.~~ **in IC 16-18-2-28.5).**

SECTION 22. IC 25-26-13-4 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. (a) The board may:

(1) promulgate rules and regulations under IC 4-22-2 for implementing and enforcing this chapter;

(2) establish requirements and tests to determine the moral, physical, intellectual, educational, scientific, technical, and professional qualifications for applicants for pharmacists' licenses;
(3) refuse to issue, deny, suspend, or revoke a license or permit or place on probation or fine any licensee or permittee under this chapter;
(4) regulate the sale of drugs and devices in the state of Indiana;
(5) impound, embargo, confiscate, or otherwise prevent from disposition any drugs, medicines, chemicals, poisons, or devices which by inspection are deemed unfit for use or would be dangerous to the health and welfare of the citizens of the state of Indiana; the board shall follow those embargo procedures found in IC 16-42-1-18 through IC 16-42-1-31, and persons may not refuse to permit or otherwise prevent members of the board or their representatives from entering such places and making such inspections;
(6) prescribe minimum standards with respect to physical characteristics of pharmacies, as may be necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public;
(7) subject to IC 25-1-7, investigate complaints, subpoena witnesses, schedule and conduct hearings on behalf of the public interest on any matter under the jurisdiction of the board;
(8) prescribe the time, place, method, manner, scope, and subjects of licensing examinations which shall be given at least twice annually; and
(9) perform such other duties and functions and exercise such other powers as may be necessary to implement and enforce this chapter.

(b) The board shall adopt rules under IC 4-22-2 for the following:
(1) Establishing standards for the competent practice of pharmacy.
(2) Establishing the standards for a pharmacist to counsel individuals regarding the proper use of drugs.
(3) Establishing standards and procedures before January 1, 2006, to ensure that a pharmacist:
(A) has entered into a contract that accepts the return of expired drugs with; or
(B) is subject to a policy that accepts the return of expired drugs of;
a wholesaler, manufacturer, or agent of a wholesaler or manufacturer concerning the return by the pharmacist to the wholesaler, the manufacturer, or the agent of expired legend drugs or controlled drugs. In determining the standards and procedures, the board may not interfere with negotiated terms related to cost, expenses, or reimbursement charges contained in contracts between parties, but may consider what is a reasonable quantity of a drug to be purchased by a pharmacy. The standards and procedures do not apply to vaccines that prevent influenza, medicine used for the treatment of malignant hyperthermia, and other drugs determined by the board to not be subject to a return policy. An agent of a wholesaler or manufacturer must be appointed in writing and

have policies, personnel, and facilities to handle properly returns of expired legend drugs and controlled substances.

(c) The board may grant or deny a temporary variance to a rule it has adopted if:

(1) the board has adopted rules which set forth the procedures and standards governing the grant or denial of a temporary variance; and

(2) the board sets forth in writing the reasons for a grant or denial of a temporary variance.

SECTION 23. IC 25-26-14-1 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. **(a)** This chapter applies to any individual, partnership, limited liability company, corporation, or business firm:

(1) located in or outside Indiana; and

(2) engaging in the wholesale distribution of legend drugs ~~within~~ **in** Indiana.

(b) Except as required by federal law or regulation, the requirements of this chapter do not apply to a manufacturer that is approved by the federal Food and Drug Administration. However, the board may adopt rules concerning manufacturers that the board considers appropriate and necessary.

SECTION 24. IC 25-26-14-1.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 1.5. As used in this chapter, "adulterated" refers to a legend drug that:**

(1) consists in whole or in part of a filthy, putrid, or decomposed substance;

(2) has been produced, prepared, packed, or held under unsanitary conditions and may have been contaminated or rendered injurious to health;

(3) has been subjected to conditions in the manufacture, processing, packing, or holding of the legend drug that do not conform to current standards of manufacturing to ensure that the legend drug is safe for use and possesses the identity, strength, quality, and purity characteristics that the legend drug is represented to possess;

(4) is contained in a container composed of a poisonous or deleterious substance that may render the legend drug injurious to health;

(5) bears or contains, for purposes of coloring only, a color additive that is unsafe;

(6) is of a different strength, quality, or purity from the official compendium standard for the legend drug; or

(7) does not meet the considerations of the federal Food, Drug, and Cosmetic Act.

SECTION 25. IC 25-26-14-1.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 1.7. As used in this chapter, "authenticate" means to affirmatively verify before distribution occurs that each transaction that is listed on:**

(1) the pedigree of a legend drug; and

(2) other accompanying documentation for a legend drug;

has occurred.

SECTION 26. IC 25-26-14-1.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 1.8. As used in this chapter, "authorized distributor" means a wholesale drug distributor with which a manufacturer has established an ongoing relationship to distribute the manufacturer's products. For purposes of this section, an ongoing relationship exists between a wholesale drug distributor, including any affiliated group (as defined in Section 1504 of the Internal Revenue Code) of which the wholesale distributor is a member, and a manufacturer if the wholesale drug distributor:**

(1) has a written agreement currently in effect with the manufacturer evidencing an ongoing relationship;

(2) is listed on the manufacturer's current monthly updated list of authorized distributors; or

(3) has a verifiable account with the manufacturer and a minimal transaction or volume requirement limit of:

(A) five thousand (5,000) units per company in the previous twelve (12) months; or

(B) twelve (12) purchases at the manufacturer's minimum purchasing requirement per invoice in the previous twelve (12) months.

SECTION 27. IC 25-26-14-4.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 4.1. As used in this chapter, "co-licensed products" means pharmaceutical products:**

(1) that have been approved by the federal Food and Drug Administration; and

(2) concerning which two (2) or more parties have the right to engage in a business activity or occupation concerning the pharmaceutical products.

SECTION 28. IC 25-26-14-4.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 4.2. As used in this chapter, "compendium" refers to:**

(1) the United States Pharmacopoeia;

(2) the Homeopathic Pharmacopoeia of the United States;

(3) the National Formulary;

(4) a drug approved by the federal Food and Drug Administration; or

(5) a supplement to a document specified in subdivision (1), (2), or (3).

SECTION 29. IC 25-26-14-4.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 4.3. As used in this chapter, "contraband" refers to a legend drug:**

(1) that is counterfeit;

(2) that is stolen;

(3) that is misbranded;

(4) that is obtained by fraud;

(5) that is purchased by a nonprofit institution for the nonprofit institution's own use and placed in commerce in violation of the own use agreement for the legend drug;

(6) for which a required pedigree does not exist; or

(7) for which a pedigree in existence:

(A) has been forged, counterfeited, or falsely created; or

(B) contains any altered, false, or misrepresented information.

SECTION 30. IC 25-26-14-4.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 4.4. As used in this chapter, "counterfeit" refers to a legend drug, or the container, seal, or labeling of a legend drug, that, without authorization, bears the trademark, trade name, or other identifying mark or imprint of a manufacturer, processor, packer, or distributor other than the person that manufactured, processed, packed, or distributed the legend drug.**

SECTION 31. IC 25-26-14-4.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 4.5. As used in this chapter, "deliver" means the actual, constructive, or attempted transfer of a legend drug from one (1) person to another.**

SECTION 32. IC 25-26-14-4.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 4.6. As used in this chapter, "designated representative" means an individual who:**

(1) is designated by a wholesale drug distributor;

(2) serves as the wholesale drug distributor's responsible individual with the board; and

(3) is actively involved in and aware of the actual daily operation of the wholesale drug distributor.

SECTION 33. IC 25-26-14-4.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 4.7. As used in this chapter, "distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a legend drug, whether by passage of title or physical movement, or both. The term does not include the following:**

(1) Dispensing or administering a legend drug.

(2) Delivering or offering to deliver a legend drug by a common carrier in the usual course of business as a common carrier.

(3) The provision of a legend drug sample to a patient by a:

(A) practitioner;

(B) health care professional acting at the direction and under the supervision of a practitioner; or

(C) hospital's or other health care entity's pharmacy that received the drug sample in accordance with this chapter and other applicable law to administer or dispense and that is acting at the direction of a practitioner;

licensed to prescribe the legend drug.

SECTION 34. IC 25-26-14-6 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 6. As used in this chapter, "health care entity" means any organization or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care. **The term does not include a pharmacy or wholesale drug distributor.**

SECTION 35. IC 25-26-14-6.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 6.5. As used in this chapter, "label" means a display of written, printed, or graphic matter on the immediate container of a legend drug.**

SECTION 36. IC 25-26-14-6.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 6.6. As used in this chapter, "labeling" means labels and other written, printed, or graphic matter:**

(1) on a legend drug or a legend drug's container or wrapper; or

(2) accompanying a legend drug.

SECTION 37. IC 25-26-14-7 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 7. As used in this chapter, "legend drug" has the meaning set forth in IC 16-18-2-199. The term includes any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to 21 U.S.C. 811 through 812. **The term does not include a device or a device component, part, or accessory.**

SECTION 38. IC 25-26-14-8.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 8.3. As used in this chapter, "misbranded" means that a legend drug's label:**

(1) is false or misleading;

(2) does not bear the name and address of the manufacturer, packer, or distributor or does not contain an accurate statement of the quantities of active ingredients of the legend drug;

(3) does not show an accurate monograph for the legend drug; or

(4) does not comply with any other requirements of the federal Food, Drug, and Cosmetic Act.

SECTION 39. IC 25-26-14-8.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 8.5. As used in this chapter, "normal distribution chain of custody" means the route that a legend drug travels:**

(1) from a manufacturer to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;

(2) from a manufacturer to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(3) from a manufacturer to a chain drug warehouse, to a

pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(4) from a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;

(5) from a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(6) from a manufacturer to a third party logistics provider, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; or

(7) as prescribed by rules adopted by the board.

SECTION 40. IC 25-26-14-8.7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 8.7. As used in this chapter, "pedigree" means a statement or record in a written or an electronic form that is approved by the board, that records each distribution of a legend drug from the sale by the manufacturer from the last authorized distributor of record through acquisition and sale by each wholesale drug distributor, and that includes information designated by the board through rules for each transaction.**

SECTION 41. IC 25-26-14-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. As used in this chapter, "person" means an individual, a partnership, a business firm, a limited liability company, ~~or~~ a corporation, **or another entity, including a governmental entity.**

SECTION 42. IC 25-26-14-9.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 9.2. As used in this chapter, "practitioner" has the meaning set forth in IC 16-42-19-5.**

SECTION 43. IC 25-26-14-9.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 9.3. As used in this chapter, "repackage" means changing the container, wrapper, quantity, or labeling of a legend drug to further the distribution of the legend drug.**

SECTION 44. IC 25-26-14-10.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 10.5. As used in this chapter, "third party logistics provider" means an entity that:**

(1) provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the legend drug or have general responsibility to direct the legend drug's sale or disposition; and

(2) is licensed under this chapter.

SECTION 45. IC 25-26-14-11 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: Sec. 11. As used in this chapter, "wholesale distribution" means ~~distribution of~~ **to distribute** legend drugs to persons other than a consumer or patient.

The term does not include:

(1) a sale **or transfer** between a division, a subsidiary, a parent, an affiliated, or a related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for the hospital's or health care entity's own use from the group purchasing organization or from other hospitals or health care entities that are members of the organization;

(3) the sale of a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale of a drug among hospitals or other health care entities that are under common control;

(5) the sale of a drug for emergency medical reasons, including transfers of legend drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, if the gross dollar value of the transfers does not exceed five percent (5%) of the total legend drug sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period;

(6) the sale of a drug or the dispensing of a drug pursuant to a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives;

(8) the sale of blood and blood components intended for transfusion;

(9) the sale of a drug by a retail pharmacy to a practitioner (as defined in IC 25-26-13-2) for office use, if the gross dollar value of the transfers does not exceed five percent (5%) of the retail pharmacy's total legend drug sales during any twelve (12) consecutive months; ~~or~~

(10) the sale of a drug by a retail pharmacy that is ending its business and liquidating its inventory to another retail pharmacy;

(11) drug returns by a hospital, health care entity, or charitable institution conducted under 21 CFR 203.23;

(12) the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use;

(13) the distribution of prescription drugs by the original manufacturer of the finished form of the prescription drug or the distribution of the co-licensed products by a partner of the original manufacturer of the finished form of the prescription drug; or

(14) drug returns that meet criteria established by rules adopted by the board.

SECTION 46. IC 25-26-14-14 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 14. (a) ~~After September 14, 1992,~~ A person may not engage in wholesale distributions of legend drugs without: ~~having~~

(1) after December 31, 2005, obtaining and maintaining accreditation or certification from the National Association of

Boards of Pharmacy's Verified Accredited Wholesale Distributor or an accreditation body approved by the board under subsection (g);

(2) obtaining and maintaining a license ~~from~~ **issued by** the board; and

(3) paying any reasonable fee required by the board.

(b) The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter.

(c) The board ~~may~~ **shall** require a separate license for

~~(1)~~ each facility ~~directly or indirectly owned or operated by the same business in Indiana; or~~

~~(2) a parent entity with divisions, subsidiaries, or affiliate companies in Indiana when operations are conducted at more than one (1) location and there exists joint ownership and control among all the entities.~~ **or location where wholesale distribution operations are conducted.**

(d) An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.

(e) The issuance of a license under this chapter does not affect tax liability imposed by the department of state revenue or the department of local government finance on any wholesale drug distributor.

(f) The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if:

(1) an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter; and

(2) the other state extends reciprocity to wholesale drug distributors licensed in Indiana.

However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter.

(g) The board may adopt rules under IC 4-22-2 to approve an accreditation body to:

(1) evaluate a wholesale drug distributor's operations to determine compliance with:

(A) professional standards;

(B) this chapter; and

(C) any other applicable law; and

(2) perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.

SECTION 47. IC 25-26-14-14.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 14.5. After June 30, 2006, a wholesale drug distributor may not accept or deliver a legend drug without a current, accompanying pedigree.**

SECTION 48. IC 25-26-14-15 IS AMENDED TO READ AS

FOLLOWS [EFFECTIVE JANUARY 1, 2006]: Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee.

(2) All trade or business names used by the licensee.

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs.

(4) The type of ownership of operation.

(5) The name of each owner and operator of the licensee, including:

(A) if an individual, the name, **address, Social Security number, and date of birth** of the individual;

(B) if a partnership, the name, **address, Social Security number, and date of birth** of each partner, and the name of the partnership **and federal employer identification number;**

(C) if a corporation:

(i) the name, **address, Social Security number, date of birth,** and title of each corporate officer and director;

(ii) the corporate names, ~~and~~ the name of the state of incorporation, **the federal employer identification number, and the name of the parent company, if any; and**

(iii) the name, address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, unless the stock is traded on a major stock exchange and not traded over the counter;

(D) if a limited liability company, the name of each manager and member, the name **and federal employer identification number** of the limited liability company, and the name of the state where organized; and

(E) if a sole proprietorship, the full name, **address, Social Security number, and date of birth** of the sole proprietor and the name **and federal employer identification number** of the business entity.

(6) The name, **address, and telephone number** of the ~~person~~ designated ~~by the licensee as responsible for the operation~~ **representative** of ~~the facilities.~~ **each facility.**

(7) Additional information concerning record keeping required under this chapter.

(b) The board shall require a wholesale drug distributor to post a surety bond of at least one hundred thousand dollars ($100,000), or an equivalent means of security acceptable to the board, including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties that may be imposed by the board and any fees and costs that may be incurred by the board and that:

(1) are related to a license held by the wholesale drug

distributor;

(2) are authorized under Indiana law; and

(3) the wholesale drug distributor fails to pay less than thirty (30) days after the penalties, fees, or costs become final.

However, a separate surety bond or an equivalent means of security is not required for a separate location or a company of the wholesale drug distributor.

(c) The board may make a claim against a bond or security posted under subsection (b) within one (1) year after the wholesale drug distributor's license is no longer valid or sixty (60) days after the conclusion of:

(1) an administrative or legal proceeding before or on behalf of the board that involves the wholesale drug distributor and results in penalties, fees, or costs described in subsection (b); or

(2) an appeal of a proceeding described in subdivision (1);

whichever occurs later.

(d) The board shall inspect each facility where wholesale distribution operations are conducted before initial licensure and periodically thereafter in accordance with a schedule determined by the board, but at least one (1) time in each three (3) year period.

(e) A wholesale drug distributor must publicly display or have readily available all licenses and the most recent inspection report administered by the board.

~~(b)~~ **(f)** A material change in any information in ~~subsection (a) of~~ this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

SECTION 49. IC 25-26-14-15.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 15.5. (a) A wholesale drug distributor that is an authorized distributor of a manufacturer is not considered to be an authorized distributor of the manufacturer under this chapter unless:**

(1) the manufacturer files the manufacturer's monthly updated list of authorized distributors with the board;

(2) the list is available from the manufacturer upon request or on the Internet; and

(3) the manufacturer notifies the board of any change to the list within ten (10) days after the change.

(b) The board shall make available on the board's Internet web site a manufacturer's list of authorized distributors filed as described in subsection (a).

SECTION 50. IC 25-26-14-16 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 16. **(a)** In reviewing, **for purposes of licensure or renewal of a license under this chapter,** the qualifications of persons who engage in wholesale distribution of legend drugs ~~within~~ **in** Indiana, the board shall consider the following factors:

(1) A ~~conviction of the applicant relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.~~ **finding by the board that the applicant has:**

(A) violated a law; or

(B) been disciplined by a regulatory agency for violating a law;

related to drug distribution in any state.

(2) A ~~felony~~ **criminal** conviction of the applicant.

(3) The applicant's past experience in the manufacture or distribution of legend drugs, including controlled substances.

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.

(5) Suspension or revocation **of any license held by the applicant or the applicant's owner or the imposition of sanctions against the applicant or the applicant's owner** by the federal or a state **or local** government ~~of any license held by the applicant~~ for the manufacture or distribution of any drugs, including controlled substances.

(6) Compliance with licensing requirements under previously granted licenses.

(7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.

(8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the granting of the license would not be in the public interest.

(b) After December 31, 2005, in reviewing an application for licensure or renewal of a license under this chapter, the board shall consider the results of a national criminal history background check (as defined in IC 10-13-3-12) for:

(1) the applicant;

(2) all personnel involved in the operations of the wholesale drug distributor;

(3) the most senior individual responsible for facility operations, purchasing, and inventory control, and the individual to whom the senior individual reports;

(4) company officers;

(5) key management personnel;

(6) principals; and

(7) owners with at least a ten percent (10%) interest in the wholesale drug distributor, if the wholesale drug distributor is a nonpublicly held company.

The national criminal history background check must be conducted at the applicant's expense and must include all states of residence since the applicant became eighteen (18) years of age.

(c) After December 31, 2005, an applicant shall provide and attest to:

(1) an affirmation that the applicant has not been involved in or convicted of any criminal or prohibited acts; or

(2) a statement providing a complete disclosure of the applicant's past criminal convictions and violations of state and federal laws;

regarding drugs.

SECTION 51. IC 25-26-14-16.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 16.5. (a) A wholesale drug distributor shall designate in writing on a form prescribed by the board a designated representative for each of the wholesale drug distributor's facilities licensed under this chapter.**

(b) A designated representative shall submit to the board an application prescribed by the board and provide to the board the following:

(1) A set of the designated representative's fingerprints, under procedures specified by the board and according to requirements of the state police department under IC 10-13-3-38.5, with payment of the amount equal to the costs of a national criminal history background check (as defined in IC 10-13-3-12) of the designated representative to be obtained by the state police department.

(2) The date and place of birth of the designated representative.

(3) A list of the occupations, positions of employment, and offices held by the designated representative during the immediately preceding seven (7) years, including the principal business and address of the organization with which the occupation, position, or office was associated.

(4) A statement concerning whether the designated representative, during the immediately preceding seven (7) years, has been temporarily or permanently enjoined by a court from violating a state or federal law regulating the possession, control, or distribution of legend drugs, including details of related events.

(5) A description of any involvement by the designated representative with a business that:

(A) manufactured, administered, prescribed, distributed, or stored legend drugs; and

(B) was named as a party in a lawsuit;

during the immediately preceding seven (7) years, including investments other than the ownership of stock in a publicly traded company or mutual fund.

(6) A description of any criminal offense of which the designated representative has been convicted, regardless of whether adjudication of guilt was withheld or whether the designated representative pleaded nolo contendere. If the designated representative indicates that a criminal conviction is under appeal, the designated representative shall submit to the board:

(A) a copy of the notice of appeal; and

(B) a copy of the final written order of disposition.

(7) A photograph of the designated representative taken within the immediately preceding thirty (30) days under procedures specified by the board.

(8) A list of the name, address, occupation, and date and place of birth of each member of the designated representative's immediate family, including the designated representative's

spouse, children, parents, and siblings, and the spouses of the designated representative's children and siblings. Information collected under this subdivision is confidential.

(9) Any other information required by the board.

(c) A designated representative must have at least two (2) years of verifiable full-time managerial or supervisory experience in a pharmacy or with a wholesale drug distributor licensed under this chapter or in another state. The designated representative's responsibilities must have included record keeping, storage, and shipment of legend drugs.

(d) A designated representative shall not serve as the designated representative for more than one (1) wholesale drug distributor facility at any one (1) time.

(e) A designated representative shall be actively involved and aware of the actual daily operations of the wholesale drug distributor as follows:

(1) Be employed full time in a managerial position by the wholesale drug distributor.

(2) Be physically present at the wholesale drug distributor's facility during normal business hours, except when absent due to illness, family illness or death, scheduled vacation, or another authorized absence.

(3) Be aware of and knowledgeable about all policies and procedures pertaining to the operations of the wholesale drug distributor.

(f) A designated representative must complete continuing education programs specified by the board regarding state and federal law relevant to the distribution, handling, and storage of legend drugs.

(g) A third party logistics provider must comply with this subsection until the third party logistics provider has obtained accreditation. A third party logistics provider must identify to the board a designated representative who is responsible for the facility's compliance with applicable state and federal law. The designated representative:

(1) may be a corporate employee or officer, outside counsel, or an outside consulting specialist with authority to help ensure compliance;

(2) may be responsible for multiple facilities; and

(3) is not required to be physically present at the facility.

SECTION 52. IC 25-26-14-16.6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 16.6. (a) A wholesale drug distributor that:**

(1) is licensed under this chapter;

(2) is located outside Indiana; and

(3) distributes legend drugs in Indiana;

shall designate an agent in Indiana for service of process.

(b) A wholesale drug distributor that does not designate an agent under subsection (a) is considered to have designated the secretary of state to be the wholesale drug distributor's true and lawful

attorney, upon whom legal process may be served in an action or a proceeding against the wholesale drug distributor arising from the wholesale drug distributor's wholesale distribution operations.

(c) The board shall mail a copy of any service of process to a wholesale drug distributor by certified mail, return receipt requested, postage prepaid, at the address designated by the wholesale drug distributor on the application for licensure submitted under this chapter.

(d) Service of process on the secretary of state is sufficient in an action or a proceeding against a wholesale drug distributor that is not licensed under this chapter.

SECTION 53. IC 25-26-14-17 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: Sec. 17. As a condition for receiving and retaining ~~any~~ **a** wholesale drug distributor license issued under ~~to~~ this chapter, ~~each~~ **an** applicant must satisfy the board that the applicant has and will continuously maintain the following:

(1) Acceptable storage and handling conditions and facilities standards **for each facility at which legend drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which legend drugs are transported, including:**

(A) suitable construction of the facility and appropriate monitoring equipment to ensure that legend drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards;

(B) suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

(C) adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(D) a quarantine area for separate storage of legend drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened;

(E) maintenance of the facility in a clean and orderly condition;

(F) maintenance of the facility in a commercial, nonresidential building; and

(G) freedom of the facility from infestation.

(2) **Security of each facility from unauthorized entry as follows:**

(A) Entry into areas where legend drugs are held is limited to authorized personnel.

(B) Each facility is equipped with a security system that includes:

~~(A)~~ **(i)** an after hours central alarm or a comparable entry detection capability;

~~(B)~~ **(ii)** restricted premises access;

~~(C)~~ **(iii)** adequate outside perimeter lighting; ~~and~~

~~(D)~~ **(iv)** safeguards against **theft and diversion, including**

employee theft **and theft or diversion facilitated or hidden by tampering with computers or electronic records; and**

(v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.

(3) A reasonable system of record keeping ~~that~~ **as follows:**

(A) **The system** describes all the wholesale distributor's activities governed by this chapter for the ~~two~~ ~~(2)~~ **three (3)** year period after the disposition of each product, and **all records are maintained for at least three (3) years after disposition of the legend drug to which the record applies.**

(B) **The system** is reasonably accessible as determined by board rules in any inspection authorized by the board.

(C) The system provides a means to establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of all legend drugs, including the following:

(i) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that leaves the normal distribution chain of custody, as determined by rules adopted by the board.

(ii) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an authorized distributor, a pedigree for each distributed legend drug.

(iii) After January 1, 2007, and after consulting with the federal Food and Drug Administration, at the board's discretion, for each legend drug received and distributed by the wholesale drug distributor, an electronic pedigree developed in accordance with standards and requirements of the board to authenticate, track, and trace legend drugs. The standards and requirements of the board may indicate the information required to be part of the electronic pedigree.

(iv) Dates of receipt and distribution or other disposition of the legend drugs by the wholesale drug distributor.

(v) Availability for inspection and photocopying by any authorized official of a local, state, or federal governmental agency for three (3) years after the creation date of the inventories and records.

(D) Onsite electronic inventories and records are immediately available for inspection, and records kept at a central location apart from the inspection site and not electronically retrievable are available for inspection within two (2) working days after a request by an authorized official of a local, state, or federal governmental agency.

(E) The system maintains an ongoing list of persons with whom the wholesale drug distributor does business.

(F) The system provides for reporting counterfeit or suspected counterfeit legend drugs or counterfeiting or

suspected counterfeiting activities to the board and the federal Food and Drug Administration.

(G) The system provides for mandatory reporting of significant shortages or losses of legend drugs to the board and the federal Food and Drug Administration if diversion is known or suspected.

(4) Written policies and procedures **to which the wholesale drug distributor adheres for the receipt, security, storage, inventory, transport, shipping, and distribution of legend drugs, and** that assure reasonable wholesale distributor preparation for, protection against, and handling of any facility security or operation problems, including **the following:**

(A) ~~those~~ **Facility security or operation problems** caused by natural disaster or government emergency.

(B) **Correction of** inventory inaccuracies. ~~or~~

(C) Product shipping and receiving **problems.**

~~(C)~~ **(D) Quarantine and return to the manufacturer or destruction in accordance with state and federal law of all** outdated ~~product~~ **products and outdated or expired legend drugs, including appropriate documentation and witnessing.**

~~(D)~~ **(E)** Appropriate disposition of returned goods. ~~and~~

~~(E)~~ **(F)** Product recalls.

(G) Identifying, recording, and reporting losses or thefts.

(H) Implementation and maintenance of a continuous quality improvement system.

(I) Recalls and withdrawals of legend drugs due to:

(i) an action initiated by the federal Food and Drug Administration or another federal, state, or local governmental agency;

(ii) a volunteer action by the manufacturer to remove defective or potentially defective legend drugs from the market; or

(iii) an action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design.

(J) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(K) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband legend drugs and reporting of discrepancies within three (3) business days to the board and any other appropriate state or federal governmental agency.

(L) Reporting of criminal or suspected criminal activities involving the inventory of legend drugs to the board within three (3) business days.

(M) Conducting for cause authentication and random authentication as required under sections 17.2, 17.3, and 17.8 of this chapter.

(5) **Written policies and procedures and** sufficient inspection procedures for all incoming and outgoing product shipments, **including the following:**

(A) Upon receipt, visual examination of each shipping container in a manner adequate to identify the legend drugs in the container and to determine whether the legend drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution.

(B) Upon receipt, review of records by the wholesale drug distributor for the acquisition of legend drugs for accuracy and completeness, considering the:

(i) total facts and circumstances surrounding each transaction involving the legend drugs; and

(ii) wholesale drug distributors involved.

(C) Quarantine of a legend drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, suspected counterfeit, damaged, or otherwise unfit for distribution until:

(i) examination and a determination that the legend drug is not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution; or

(ii) the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(D) Written policies and procedures to ensure that a legend drug that was:

(i) ordered in error or in excess of need by the wholesale drug distributor;

(ii) identified within three (3) business days after receipt as ordered in error or in excess of need; and

(iii) maintained such that the legend drug's integrity has not been compromised;

may be returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired if the appropriate documentation is completed and necessary notations are made to a required pedigree.

(E) Written policies and procedures to ensure that if the wholesale drug distributor determines that a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

(F) Written policies and procedures to ensure that if the immediate or sealed outer or secondary container or labeling of a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor:

(i) quarantines the legend drug until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired; and

(ii) provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

(G) Written policies and procedures to ensure that a legend drug that has been opened or used, but is not adulterated, misbranded, counterfeit, or suspected counterfeit, is identified as such and quarantined until the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(H) Written policies and procedures to ensure that:

(i) a legend drug that will be returned to a manufacturer or wholesale drug distributor is kept under proper conditions for storage, handling, transport, and shipment before the return; and

(ii) documentation showing that proper conditions were maintained is provided to the manufacturer or wholesale drug distributor to which the legend drug is returned.

(I) Inspection of each outgoing shipment for identity of the legend drugs and to ensure that the legend drugs have not been damaged in storage or held under improper conditions.

(J) Written policies and procedures to ensure that if conditions under which a legend drug has been returned to the wholesale drug distributor cast doubt on the legend drug's safety, identity, strength, quality, or purity, the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired unless examination, testing, or other investigation proves that the legend drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a legend drug has been returned cast doubt on the legend drug's safety, identity, strength, quality, or purity, the wholesale drug distributor considers the conditions under which the legend drug has been held, stored, or shipped before or during the legend drug's return and the condition of the legend drug and the legend drug's container, carton, or labeling upon receipt of the returned legend drug.

(K) Written policies and procedures to ensure that contraband, counterfeit, or suspected counterfeit legend drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the board and the federal Food and Drug Administration.

(L) Written policies and procedures to ensure that any shipping, immediate, or sealed outer or secondary container

or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent, are retained until a disposition is authorized by the board and the federal Food and Drug Administration.

(6) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(7) Written policies and procedures to provide for the secure and confidential storage of information with restricted access and to protect the integrity and confidentiality of the information.

(8) A pedigree as required under this chapter, including an electronic pedigree developed in accordance with standards and requirements of the board under subdivision (3)(C)(iii).

(9) Appropriate inventory management and control systems to:

(A) prevent; and

(B) allow detection and documentation of;

theft, counterfeiting, or diversion of legend drugs.

(10) If the wholesale drug distributor is involved in the distribution of controlled substances, registration with the federal Drug Enforcement Administration and the board and compliance with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances.

(11) Isolation of controlled substances from noncontrolled substances and storage of the controlled substances in a secure area in accordance with federal Drug Enforcement Administration security requirements and standards.

(12) Technology and equipment that allow the wholesale drug distributor to authenticate, track, and trace legend drugs. The technology and equipment meet standards set by the board and are used as required by the board to conduct for cause and random tracking, tracing, and authentication of legend drugs.

(13) Employment, training, and documentation of the training concerning the proper use of the technology and equipment required under subdivision (12).

(14) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs due to tampering or adverse storage conditions.

SECTION 54. IC 25-26-14-17.2 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 17.2. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor and has reason to believe that a legend drug purchased from the other wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.**

(b) A wholesale drug distributor that has engaged in the distribution of a legend drug for which a purchasing wholesale drug distributor conducts a for cause authentication under subsection (a) shall provide, upon request, detailed information

regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and electronic mail address of the wholesale drug distributor that sold the legend drug.

(c) If a wholesale drug distributor conducts a for cause authentication under subsection (a) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

(d) If a wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (a), the wholesale drug distributor shall maintain records of the authentication for three (3) years and shall produce the records for the board and the federal Food and Drug Administration upon request.

SECTION 55. IC 25-26-14-17.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 17.3. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor shall, at least annually, conduct a random authentication of a required pedigree on at least ten percent (10%) of sales units of wholesale distributions of legend drugs purchased from other wholesale drug distributors.**

(b) A wholesale drug distributor from whom another wholesale drug distributor purchases legend drugs shall cooperate with random authentications of pedigrees described in this section and provide requested information in a timely manner.

(c) If a wholesale drug distributor conducts a random authentication under this section and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 56. IC 25-26-14-17.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 17.8. (a) A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required under this section and rules adopted by the board.**

(b) Before the initial purchase of legend drugs from the unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall obtain the following information from the unlicensed wholesale drug distributor:

(1) A list of states in which the unlicensed wholesale drug

distributor is licensed.

(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.

(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.

(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.

(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.

(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.

(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.

(8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.

(9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.

(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.

(11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.

(13) A statement:

(A) as to whether; and

(B) of the identity of each manufacturer for which;

the unlicensed wholesale drug distributor is an authorized distributor.

(c) Before the initial purchase of legend drugs from an unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall:

(1) request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department of all individuals associated with the unlicensed wholesale drug distributor as specified for licensure of a wholesale drug distributor under section 16(b) of this chapter; and

(2) verify the unlicensed wholesale drug distributor's status as an authorized distributor, if applicable.

(d) If an unlicensed wholesale drug distributor's facility has not been inspected by the board or the board's agent within three (3) years after a contemplated purchase described in subsection (a), the licensed wholesale drug distributor shall conduct an inspection of the unlicensed wholesale drug distributor's facility:

(1) before the initial purchase of legend drugs from the

unlicensed wholesale drug distributor; and

(2) at least once every three (3) years unless the unlicensed wholesale drug distributor's facility has been inspected by the board, or the board's agent, during the same period;

to ensure compliance with applicable laws and regulations relating to the storage and handling of legend drugs. A third party may be engaged to conduct the site inspection on behalf of the licensed wholesale drug distributor.

(e) At least annually, a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall ensure that the unlicensed wholesale drug distributor maintains a record keeping system that meets the requirements of section 17(3) of this chapter.

(f) If a licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor has reason to believe that a legend drug purchased from the unlicensed wholesale drug distributor is misbranded, adulterated, counterfeit, or suspected counterfeit, the licensed wholesale drug distributor shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

(g) An unlicensed wholesale drug distributor that has engaged in the distribution of a legend drug for which a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) shall provide, upon request, detailed information regarding the distribution of the legend drug, including the:

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

(3) sales invoice number of the legend drug; and

(4) contact information, including name, address, telephone number, and any electronic mail address of the unlicensed wholesale drug distributor that sold the legend drug.

(h) If a licensed wholesale drug distributor conducts a for cause authentication under subsection (f) and is unable to authenticate each distribution of the legend drug, the licensed wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration within ten (10) business days after completing the attempted authentication.

(i) If a licensed wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (f), the licensed wholesale drug distributor shall maintain records of the authentication for three (3) years and shall provide the records to the board upon request.

(j) A licensed wholesale drug distributor that purchases legend drugs from an unlicensed wholesale drug distributor shall, at least annually, conduct random authentications of required pedigrees on at least ten percent (10%) of sales units of distributions of legend drugs that were purchased from unlicensed wholesale drug distributors.

(k) An unlicensed wholesale drug distributor from which a licensed wholesale drug distributor has purchased legend drugs

shall cooperate with the random authentications of pedigrees under this section and provide requested information in a timely manner.

(l) If a wholesale drug distributor conducts a random authentication under subsection (j) and is unable to authenticate each distribution of the legend drug, the wholesale drug distributor shall quarantine the legend drug and report the circumstances to the board and the federal Food and Drug Administration not more than ten (10) business days after completing the attempted authentication.

SECTION 57. IC 25-26-14-17.9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 17.9. A wholesale drug distributor licensed under this chapter may not use a trade name or business name identical to a trade name or business name used by another wholesale drug distributor licensed under this chapter.**

SECTION 58. IC 25-26-14-20 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 20. **(a)** A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.

(b) After December 31, 2005, before employing a person to be engaged in the operation and handling of legend drugs, a wholesale drug distributor shall request that the board obtain and consider the results of a national criminal history background check (as defined in IC 10-13-3-12) through the state police department for the person.

SECTION 59. IC 25-26-14-21.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]: **Sec. 21.5. (a) A person may not perform, cause the performance of, or aid the performance of the following:**

(1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a legend drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.

(2) The adulteration, misbranding, or counterfeiting of a legend drug.

(3) The receipt of a legend drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the legend drug for pay or otherwise.

(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a legend drug or the commission of another act with respect to a legend drug that results in the legend drug being misbranded.

(5) Forging, counterfeiting, simulating, or falsely representing a legend drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.

(6) The purchase or receipt of a legend drug from a person that is not licensed to distribute legend drugs to the purchaser or

recipient.

(7) The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the legend drug to purchase or receive legend drugs from the person selling or transferring the legend drug.

(8) Failure to maintain or provide records as required under this chapter.

(9) Providing the board, a representative of the board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to this chapter.

(10) The wholesale distribution of a legend drug that was:

(A) purchased by a public or private hospital or other health care entity;

(B) donated or supplied at a reduced price to a charitable organization; or

(C) stolen or obtained by fraud or deceit.

(11) Obtaining or attempting to obtain a legend drug by fraud, deceit, misrepresentation, or engaging in fraud, deceit, or misrepresentation in the distribution of a legend drug.

(12) Failure to obtain, authenticate, or provide a required pedigree.

(13) The receipt of a legend drug through wholesale distribution without first receiving a required pedigree attested to as accurate and complete by the wholesale drug distributor.

(14) Distributing a legend drug that was previously dispensed by a retail pharmacy or distributed by a practitioner.

(15) Failure to report an act prohibited by this section.

(b) The board may impose the following sanctions if, after a hearing under IC 4-21.5-3, the board finds that a person has violated subsection (a):

(1) Revoke the wholesale drug distributor's license issued under this chapter if the person is a wholesale drug distributor.

(2) Assess a civil penalty against the person. A civil penalty assessed under this subdivision may not be more than ten thousand dollars ($10,000) per violation.

SECTION 60. IC 25-26-14-26 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 26. **(a)** A person ~~that~~ **who knowingly or intentionally** engages in the wholesale distribution of a legend drug without a license issued under this chapter commits a Class D felony.

(b) A person who engages in the wholesale distribution of a legend drug and:

(1) who, with intent to defraud or deceive:

(A) fails to obtain or deliver to another person a complete and accurate required pedigree concerning a legend drug before:

(i) obtaining the legend drug from another person; or

(ii) transferring the legend drug to another person; or

(B) falsely swears or certifies that the person has authenticated any documents related to the wholesale

distribution of legend drugs;

(2) who knowingly or intentionally:

(A) destroys, alters, conceals, or fails to maintain a complete and accurate required pedigree concerning a legend drug in the person's possession;

(B) purchases or receives legend drugs from a person not authorized to distribute legend drugs in wholesale distribution;

(C) sells, barters, brokers, or transfers a legend drug to a person not authorized to purchase the legend drug in the jurisdiction in which the person receives the legend drug in a wholesale distribution;

(D) forges, counterfeits, or falsely creates a pedigree;

(E) falsely represents a factual matter contained in a pedigree; or

(F) fails to record material information required to be recorded in a pedigree; or

(3) who:

(A) possesses a required pedigree concerning a legend drug;

(B) knowingly or intentionally fails to authenticate the matters contained in the pedigree as required; and

(C) distributes or attempts to further distribute the legend drug;

commits a Class D felony.

SECTION 61. IC 25-26-14-27 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 27. A wholesale drug distributor that fails to comply with the conditions **and requirements** described in:

(1) section 17; **or**

(2) after December 31, 2005, section 17.2, 17.3, 17.8, 17.9, or 20; of this chapter commits a Class D felony.

SECTION 62. IC 25-33-1-9 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 9. (a) The board shall issue a license to practice psychology to an individual who:

(1) applies in the manner required by the board;

(2) pays a fee;

(3) is at least eighteen (18) years of age;

(4) has not been convicted of a crime that has a direct bearing on the individual's ability to practice competently;

(5) holds, at the time of application, a valid license or certificate as a psychologist from another state;

(6) possesses a doctoral degree from a recognized institution of higher learning;

(7) has successfully completed:

(A) a degree program that would have been approved by the board at the time the individual was licensed or certified in the other state; or

(B) if the individual was licensed or certified in the other state before July 1, 1969, a degree program that satisfied the educational requirements of the board in effect January 4, 1971;

(8) has practiced psychology continuously since being licensed or

certified;

(9) if the individual was licensed or certified by the other state:

(A) after September 30, 1972, has taken the Examination for the Professional Practice of Psychology and achieved the passing score required by the board at the time the examination was administered; **or**

(B) before January 1, 1990, and the other state required an examination other than the Examination for the Professional Practice of Psychology, and the individual achieved a passing score in the other state at the time of licensure or certification;

(10) has passed an examination administered by the board that covers Indiana law related to the practice of psychology; and

(11) is not in violation of this chapter or rules adopted under this chapter.

(b) The board may adopt rules under IC 4-22-2 concerning the issuance of a license under this section.

SECTION 63. IC 25-35.6-1-2 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 2. (a) As used in this article, "board" means the speech-language pathology and audiology board established by this article.

(b) As used in this article, "person" means any individual, organization, or corporate body, except that only an individual may be licensed under this article.

(c) As used in this article, "speech-language pathologist" means an individual who practices speech-language pathology and who presents himself to the public by any title or description of services incorporating the words speech pathologist, speech-language pathologist, speech therapist, **speech-language specialist, teacher of communication disorders,** speech correctionist, speech clinician, language pathologist, language therapist, logopedist, communicologist, voice therapist, voice pathologist, or any similar title or description of service.

(d) As used in this article, "speech-language pathology" means the application of nonmedical and nonsurgical principles, methods, and procedures for the ~~measurement, testing, evaluation, prediction, counseling, instruction, habilitation, or rehabilitation related to the development and disorders of speech, voice, or language for the purpose of evaluating, preventing, ameliorating, or modifying such disorders and conditions in individuals or groups of individuals.~~ **following:**

(1) The prevention, evaluation, habilitation, rehabilitation, instruction, and research of communication and swallowing disorders.

(2) The elective modification of communication behaviors.

(3) The enhancement of communication, including the use of augmentative or alternate communication strategies.

(e) As used in this article, "audiologist" means an individual who practices audiology and who presents himself to the public by any title or description of services incorporating the words audiologist, hearing clinician, hearing therapist, **hearing specialist, audiometrist,**

vestibular specialist, or any similar title or description of service.

(f) As used in this article, "audiology" means the application of nonmedical and nonsurgical principles, methods, and procedures of ~~measurement, testing, evaluation, prediction, consultation, counseling, instruction, habilitation, or rehabilitation related to hearing and disorders of hearing for the purpose of evaluating, identifying, preventing, ameliorating, or modifying such disorders and conditions in individuals or groups of individuals.~~ **prevention, evaluation, habilitation, rehabilitation, instruction, and research of disorders of hearing, auditory function, and vestibular function.**

(g) As used in this article, ~~"speech-language pathology aide"~~ **"support personnel"** means ~~an individual~~ **individuals** who ~~meets minimum~~ **meet the** qualifications which the board ~~may~~ **shall** establish for **the following:**

(1) Speech-language pathology ~~aides.~~ **aide.**

(2) Speech-language pathology associate.

(3) Speech-language pathology assistant.

~~which qualifications shall be less than those established by this article as necessary for licensure as a speech-language pathologist, and who works under the direct supervision of a licensed speech pathologist.~~

(h) As used in this article, "audiology ~~aide"~~ **assistant"** means an individual who:

(1) is not licensed as an audiologist under this article;

(2) meets ~~minimum~~ qualifications which the board may establish; ~~for audiology aides, which qualifications shall be less than those established by this article as necessary for licensure as an audiologist, and who works~~ **and**

(3) provides specific services under the ~~direct~~ **direction and** supervision of a licensed audiologist.

(i) As used in this article, "clinical fellowship" means a supervised professional experience.

(j) As used in this article, "direct supervision" means onsite observation and guidance while an assigned evaluation or therapeutic activity is being performed.

SECTION 64. IC 25-35.6-1-4 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 4. Nothing in this article shall be construed as preventing or restricting the following:

(1) A physician or surgeon from engaging in the practice of medicine in this state, or a person under the supervision and control of a physician or surgeon from conducting hearing testing, provided such a person is not called an audiologist.

(2) Any hearing aid dealer from:

(A) engaging in the testing of hearing and other practices and procedures necessary for the business for which the dealer is registered in this state under IC 25-20-1; **and**

(B) using the title hearing aid specialist or any similar title or description of service.

(3) Any person licensed or registered in this state by any other law from engaging in the profession or occupation for which the person is licensed or registered.

(4) A person ~~who holds a valid and current credential as a~~

~~speech-language or hearing specialist issued by the department of education, or a person~~ employed as a speech-language pathologist or audiologist by the government of the United States, if such person performs speech-language pathology or audiology services solely within the confines or under the jurisdiction of the governmental ~~or state educational~~ organization by which the person is employed. However, such person may, without obtaining a license under this article, consult with or disseminate the person's research findings and other scientific information to speech-language pathologists and audiologists outside the jurisdiction of the organization by which the person is employed. Such person may also offer **instruction and** lectures to the public ~~for a fee, monetary or other,~~ without being licensed under this article. Such person may additionally elect to be subject to this article.

(5) The activities and services of persons pursuing a course of study leading to a degree in speech-language pathology **or audiology** at a college or university, if:

(A) such activities and services constitute a part of a supervised course of study; ~~and that~~

(B) such person is designated speech-language pathology **or audiology** intern, speech-language pathology **or audiology** trainee, or by other such titles clearly indicating the training status appropriate to the person's level of training; **and**

(C) the person works only under the supervision of a speech-language pathologist or audiologist licensed under this article.

~~(6) The activities and services of a person pursuing a course of study leading to a degree in audiology at a college or university, if such activities and services constitute a part of a supervised course of study and such person is designated audiology intern, audiology trainee, or by any other such titles clearly indicating the training status appropriate to the person's level of training.~~

~~(7)~~ **(6)** The activities and services of persons fulfilling the clinical experience requirement of section ~~5(a)(5)~~ **5(2)(B)(ii) or 6(3)(B)** of this chapter, if such activities and services constitute a part of the experience required for that section's fulfillment.

~~(8)~~ **(7)** The performance of pure tone air conduction testing by an industrial audiometric technician, as defined by federal law, who is working in an industrial hearing conservation program directed by a physician or an audiologist.

~~(9)~~ **(8)** The performance of speech-language pathology or audiology services in this state by any person not a resident of this state who is not licensed under this article, if such services are performed for no more than five (5) days in any calendar year and in cooperation with a speech-language pathologist or audiologist licensed under this article, and if such person meets the qualifications and requirements for application for licensure described in ~~sections 5(a)(1) and 5(a)(2)~~ **sections 5(1) and 5(2) or 6(1) and 6(2)** of this chapter. However, a person not a resident of this state who is not licensed under this article, but who is licensed

under the law of another state which has established licensure requirements at least equivalent to those established by section 5 **or 6** of this chapter or who is the holder of a certificate of clinical competence in speech-language pathology or audiology or its equivalent issued by a nationally recognized association for speech-language ~~and~~ **or** hearing, may offer speech-language pathology or audiology services in this state for no more than thirty (30) days in any calendar year, if such services are performed in cooperation with a speech-language pathologist or audiologist licensed under this article.

SECTION 65. IC 25-35.6-1-5 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 5. To be eligible for licensure by the board as a speech-language pathologist or ~~audiologist,~~ **registration as a speech-language pathology aide, a speech-language pathology associate, or a speech-language pathology assistant,** a person must satisfy the following:

(1) Not have been convicted of a crime that has a direct bearing on the person's ability to practice competently.

(2) **For licensure as a speech-language pathologist:**

(A) possess at least a master's degree or its equivalent in the area of speech-language pathology ~~or audiology, as the case may be,~~ from an educational institution recognized by the board; **and**

(B) submit evidence of:

(i) a national certification in speech-language pathology that is approved by the board; or

(ii) satisfaction of the academic and clinical experience requirements necessary for licensure as defined in the rules of the board.

(3) For registration as a speech-language pathology aide, possess at least a high school degree or its equivalent.

(4) For registration as a speech-language pathology associate, possess at least an associate degree in speech-language pathology.

(5) For registration as a speech-language pathology assistant, possess at least a bachelor's degree in speech-language pathology.

~~(3) Submit to the board transcripts from one (1) or more of the educational institutions described in subdivision (2) evidencing completion of at least eighteen (18) semester hours in courses providing fundamental information applicable to the normal development of speech, hearing, and language and at least forty-two (42) semester hours in courses providing information about and practical experience in the management of speech, hearing, and language disorders, and of these forty-two (42) semester hours:~~

~~(A) no fewer than six (6) shall be in audiology for a person applying for licensure in speech-language pathology;~~

~~(B) no fewer than six (6) shall be in speech-language pathology for a person applying for licensure in audiology;~~

~~(C) no more than six (6) shall be in courses providing academic credit for clinical practice;~~

~~(D) at least twenty-four (24), not including credits for thesis or dissertation requirements, shall be in the field for which the license is sought; and~~

~~(E) at least thirty (30) shall be in courses considered by the educational institution in which they are conducted as acceptable for application toward a graduate degree.~~

~~(4) Submit to the board evidence of the completion of at least three hundred (300) hours of supervised, direct clinical experience with a variety of communication disorders, which experience is received within the educational institution itself or a clinical program with which it cooperates.~~

~~(5) Submit to the board evidence of the completion of at least nine (9) consecutive months, at no less than thirty (30) hours per week, of clinical experience in the professional area (speech-language pathology and audiology) for which a license is sought. This requirement may also be fulfilled by part-time clinical experience as follows: fifteen (15) to nineteen (19) hours per week for eighteen (18) consecutive months; twenty (20) to twenty-four (24) hours per week for fifteen (15) consecutive months; or twenty-five (25) to twenty-nine (29) hours per week for twelve (12) consecutive months. The clinical experience must be under the direct supervision of and attested to in a notarized statement by a person licensed in the area (speech-language pathology or audiology) for which a license is being sought. Such clinical experience must additionally follow the completion of the requirements described in subdivisions (2), (3), and (4).~~

~~(6) Pass a written examination approved by the board.~~

SECTION 66. IC 25-35.6-1-6 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 6. To be eligible for an initial license by the board as an audiologist, an individual must satisfy the following:**

(1) Not have been convicted of a crime that has a direct bearing on the individual's ability to practice competently.

(2) Possess a doctoral degree from an accredited educational program recognized by the board.

(3) Submit evidence of:

(A) a national certification in audiology that is approved by the board; or

(B) satisfaction of the academic and clinical experience requirements necessary for licensure as defined in the rules of the board.

SECTION 67. IC 25-35.6-1-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 7. (a) The professional standards board may issue an initial license as a speech-language pathologist only to an individual who is licensed as a speech-language pathologist under this article. The professional standards board shall issue a license as a speech-language pathologist to an individual who:**

(1) is licensed as a speech-language pathologist under this

article; and

(2) requests licensure.

(b) A speech-language pathologist licensed by the professional standards board shall register with the health professions bureau all speech-language pathology support personnel that the speech-language pathologist supervises.

(c) The professional standards board may not impose different or additional supervision requirements upon speech-language pathology support personnel than the supervision requirements that are imposed under this article.

(d) The professional standards board may not impose continuing education requirements upon an individual who receives a license under this section that are different from or in addition to the continuing education requirements imposed under this article.

(e) An individual who:

(1) if:

(A) the individual is a speech-language pathologist, receives a license under this section or received a license as a speech-language pathologist issued by the professional standards board before July 1, 2005; or

(B) the individual is an audiologist, works in an educational setting;

(2) has been the holder of a certificate of clinical competence in speech-language pathology or audiology or its equivalent issued by a nationally recognized association for speech-language pathology and audiology for at least three (3) consecutive years; and

(3) has professional experience as a licensed speech-language pathologist or audiologist in a school setting that is equivalent to the experience required for a teacher seeking national certification by the National Board of Professional Teaching Standards;

is considered to have the equivalent of and is entitled to the same benefits that accrue to a holder of a national certification issued by the National Board for Professional Teaching Standards.

SECTION 68. IC 25-35.6-1-8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 8. (a) The board shall adopt rules under IC 4-22-2 to define the role of support personnel, including the following:**

(1) Supervisory responsibilities of the speech-language pathologist.

(2) Ratio of support personnel to speech-language pathologists.

(3) Scope of duties and restrictions of responsibilities for each type of support personnel.

(4) Frequency, duration, and documentation of supervision.

(5) Education and training required to perform services.

(6) Procedures for renewing registration and terminating duties.

(b) A speech-language pathologist must meet the following qualifications to supervise speech-language pathology support

personnel:

(1) Hold a current license as a speech-language pathologist.

(2) Have at least three (3) years of clinical experience.

(3) Hold a certificate of clinical competence in speech-language pathology or its equivalent issued by a nationally recognized association for speech-language and hearing.

(c) Speech-language pathology support personnel may provide support services only under the supervision of a speech-language pathologist.

SECTION 69. IC 25-35.6-1-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 9. (a) If a speech-language pathologist performs an evaluation and the evaluation suggests the possibility of a condition that requires medical attention, the speech-language pathologist shall promptly refer the patient to an individual licensed under IC 25-22.5.**

(b) A speech-language pathologist shall perform instrumental procedures using rigid or flexible endoscopes only under the authorization and general supervision of an individual licensed under IC 25-22.5.

SECTION 70. IC 25-35.6-1-10 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 10. (a) If an audiologist performs an evaluation and the evaluation suggests the possibility of a condition that requires medical attention, the audiologist shall promptly refer the patient to an individual licensed under IC 25-22.5.**

(b) An audiologist shall administer tests of vestibular function only to patients who have been referred by an individual licensed under IC 25-22.5.

SECTION 71. IC 25-35.6-2-2 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 2. (a) The board:

(1) shall administer, coordinate, and enforce this article;

(2) shall evaluate the qualifications and supervise the examinations of applicants for licensure under this article;

(3) may issue subpoenas, examine witnesses, and administer oaths; and

(4) shall, at its discretion, investigate allegations of practices violating this article, subject to IC 25-1-7.

(b) The board shall adopt rules under IC 4-22-2 relating to professional conduct commensurate with the policy of this article, including rules that establish standards for the competent practice of speech-language pathology and audiology. Following their adoption, the rules govern and control the professional conduct of every person who holds a license to practice speech-language pathology or audiology in this state.

(c) The board shall conduct the hearings and keep the records and minutes necessary for the orderly dispatch of its functions. The board shall have notice provided to the appropriate persons in a manner it considers appropriate of the times and places of all hearings authorized by this subsection. Approval by a majority of a quorum of the board is

required for any action to be taken in actions for revocation or suspension of a license issued under this article.

(d) The board may adopt rules under IC 4-22-2 to:

(1) administer or enforce this article;

(2) register persons in the process of fulfilling the clinical experience required for a license under this article;

(3) establish fees in accordance with IC 25-1-8-2; and

(4) register speech-language pathology **assistants, associates,** and ~~audiology~~ aides and establish rules governing the duties of **assistants, associates, and** aides.

(e) The conferral or enumeration of specific powers elsewhere in this article shall not be construed as a limitation of the general functions conferred by this section.

SECTION 72. IC 25-35.6-3-3 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 3. (a) The board ~~may waive the examination and grant licensure~~ **shall issue a license in speech-language pathology or audiology** to any applicant who:

(1) presents proof of:

(A) current licensure **in speech-language pathology or audiology** in another state, including the District of Columbia or **a** territory of the United States, ~~which maintains~~ **under** professional standards ~~considered by~~ **that** the board **considers** to be **at least** equivalent to those set forth in this article **at the time that the license was issued in the other state or territory; or**

(B) practice as a speech-language pathologist or an audiologist under the authority and supervision of an agency of the federal government; and

(2) meets any other requirements that the board establishes by rule.

(b) The board may waive the examination and grant licensure to any person certified as clinically competent by a nationally recognized association for speech-language and hearing in the area for which such person is applying for licensure.

SECTION 73. IC 25-35.6-3-3.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 3.5. The board may issue a provisional license in audiology to an individual who meets the requirements that the board establishes by rule.**

SECTION 74. IC 25-35.6-3-8.1 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: **Sec. 8.1. (a) Each individual licensed under this article and each individual registered as a speech-language pathology aide, a speech-language pathology associate, or a speech-language pathology assistant shall make the license or registration, or an official duplicate of the license or registration, available when the individual practices speech-language pathology or audiology or provides support services.**

(b) Before support personnel may provide services, the speech-language pathologist shall ensure that prior written notification is provided to the recipient of the services that services

are to be provided in whole or in part by support personnel.

SECTION 75. IC 34-24-1-1, AS AMENDED BY SEA 47-2005, SECTION 1, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2005]: Sec. 1. (a) The following may be seized:

(1) All vehicles (as defined by IC 35-41-1), if they are used or are intended for use by the person or persons in possession of them to transport or in any manner to facilitate the transportation of the following:

(A) A controlled substance for the purpose of committing, attempting to commit, or conspiring to commit any of the following:

(i) Dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-1).

(ii) Dealing in a schedule I, II, or III controlled substance (IC 35-48-4-2).

(iii) Dealing in a schedule IV controlled substance (IC 35-48-4-3).

(iv) Dealing in a schedule V controlled substance (IC 35-48-4-4).

(v) Dealing in a counterfeit substance (IC 35-48-4-5).

(vi) Possession of cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-6).

(vii) Dealing in paraphernalia (IC 35-48-4-8.5).

(viii) Dealing in marijuana, hash oil, or hashish (IC 35-48-4-10).

(B) Any stolen (IC 35-43-4-2) or converted property (IC 35-43-4-3) if the retail or repurchase value of that property is one hundred dollars ($100) or more.

(C) Any hazardous waste in violation of IC 13-30-6-6.

(D) A bomb (as defined in IC 35-41-1-4.3) or weapon of mass destruction (as defined in IC 35-41-1-29.4) used to commit, used in an attempt to commit, or used in a conspiracy to commit an offense under IC 35-47 as part of or in furtherance of an act of terrorism (as defined by IC 35-41-1-26.5).

(2) All money, negotiable instruments, securities, weapons, communications devices, or any property used to commit, used in an attempt to commit, or used in a conspiracy to commit an offense under IC 35-47 as part of or in furtherance of an act of terrorism or commonly used as consideration for a violation of IC 35-48-4 (other than items subject to forfeiture under IC 16-42-20-5 or IC 16-6-8.5-5.1 before its repeal):

(A) furnished or intended to be furnished by any person in exchange for an act that is in violation of a criminal statute;

(B) used to facilitate any violation of a criminal statute; or

(C) traceable as proceeds of the violation of a criminal statute.

(3) Any portion of real or personal property purchased with money that is traceable as a proceed of a violation of a criminal statute.

(4) A vehicle that is used by a person to:

(A) commit, attempt to commit, or conspire to commit;

(B) facilitate the commission of; or

(C) escape from the commission of;

murder (IC 35-42-1-1), kidnapping (IC 35-42-3-2), criminal confinement (IC 35-42-3-3), rape (IC 35-42-4-1), child molesting (IC 35-42-4-3), or child exploitation (IC 35-42-4-4), or an offense under IC 35-47 as part of or in furtherance of an act of terrorism.

(5) Real property owned by a person who uses it to commit any of the following as a Class A felony, a Class B felony, or a Class C felony:

(A) Dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine (IC 35-48-4-1).

(B) Dealing in a schedule I, II, or III controlled substance (IC 35-48-4-2).

(C) Dealing in a schedule IV controlled substance (IC 35-48-4-3).

(D) Dealing in marijuana, hash oil, or hashish (IC 35-48-4-10).

(6) Equipment and recordings used by a person to commit fraud under IC 35-43-5-4(11).

(7) Recordings sold, rented, transported, or possessed by a person in violation of IC 24-4-10.

(8) Property (as defined by IC 35-41-1-23) or an enterprise (as defined by IC 35-45-6-1) that is the object of a corrupt business influence violation (IC 35-45-6-2).

(9) Unlawful telecommunications devices (as defined in IC 35-45-13-6) and plans, instructions, or publications used to commit an offense under IC 35-45-13.

(10) Any equipment used or intended for use in preparing, photographing, recording, videotaping, digitizing, printing, copying, or disseminating matter in violation of IC 35-42-4-4.

(11) Destructive devices used, possessed, transported, or sold in violation of IC 35-47.5.

(12) Cigarettes that are sold in violation of IC 24-3-5.2, cigarettes that a person attempts to sell in violation of IC 24-3-5.2, and other personal property owned and used by a person to facilitate a violation of IC 24-3-5.2.

(13) Tobacco products that are sold in violation of IC 24-3-5, tobacco products that a person attempts to sell in violation of IC 24-3-5, and other personal property owned and used by a person to facilitate a violation of IC 24-3-5.

(14) Property used by a person to commit counterfeiting or forgery in violation of IC 35-43-5-2.

(15) After December 31, 2005, if a person is convicted of an offense specified in IC 25-26-14-26(b) or IC 35-43-10, the following real or personal property:

(A) Property used or intended to be used to commit, facilitate, or promote the commission of the offense.

(B) Property constituting, derived from, or traceable to the gross proceeds that the person obtained directly or indirectly as a result of the offense.

(b) A vehicle used by any person as a common or contract carrier in the transaction of business as a common or contract carrier is not subject to seizure under this section, unless it can be proven by a preponderance of the evidence that the owner of the vehicle knowingly

permitted the vehicle to be used to engage in conduct that subjects it to seizure under subsection (a).

(c) Equipment under subsection (a)(10) may not be seized unless it can be proven by a preponderance of the evidence that the owner of the equipment knowingly permitted the equipment to be used to engage in conduct that subjects it to seizure under subsection (a)(10).

(d) Money, negotiable instruments, securities, weapons, communications devices, or any property commonly used as consideration for a violation of IC 35-48-4 found near or on a person who is committing, attempting to commit, or conspiring to commit any of the following offenses shall be admitted into evidence in an action under this chapter as prima facie evidence that the money, negotiable instrument, security, or other thing of value is property that has been used or was to have been used to facilitate the violation of a criminal statute or is the proceeds of the violation of a criminal statute:

(1) IC 35-48-4-1 (dealing in or manufacturing cocaine, a narcotic drug, or methamphetamine).

(2) IC 35-48-4-2 (dealing in a schedule I, II, or III controlled substance).

(3) IC 35-48-4-3 (dealing in a schedule IV controlled substance).

(4) IC 35-48-4-4 (dealing in a schedule V controlled substance) as a Class B felony.

(5) IC 35-48-4-6 (possession of cocaine, a narcotic drug, or methamphetamine) as a Class A felony, Class B felony, or Class C felony.

(6) IC 35-48-4-10 (dealing in marijuana, hash oil, or hashish) as a Class C felony.

SECTION 76. IC 35-43-10 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JANUARY 1, 2006]:

Chapter 10. Legend Drug Deception

Sec. 1. The definitions in IC 25-26-14 apply throughout this chapter.

Sec. 2. Except as provided by federal law or regulation, this chapter does not apply to a pharmaceutical manufacturer that is approved by the federal Food and Drug Administration.

Sec. 3. A person who knowingly or intentionally:

(1) possesses a contraband legend drug;

(2) sells, delivers, or possesses with intent to sell or deliver a contraband legend drug;

(3) forges, counterfeits, or falsely creates a label for a legend drug or falsely represents a factual matter contained on a label of a legend drug; or

(4) manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug;

commits legend drug deception, a Class D felony.

Sec. 4. A person:

(1) who knowingly or intentionally manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug; and

(2) whose act under subdivision (1) results in the death of an

individual;

commits legend drug deception resulting in death, a Class A felony.

SECTION 77. IC 16-27-1-0.5 IS REPEALED [EFFECTIVE JULY 1, 2005].

SECTION 78. [EFFECTIVE JULY 1, 2005] **(a) The definitions in IC 16-27-4, as added by this act, apply to this SECTION.**

(b) Notwithstanding IC 16-27-4, as added by this act, a person is not required to be licensed by the state department of health to operate a personal services agency before January 1, 2006.

(c) This SECTION expires January 1, 2006.

SECTION 79. [EFFECTIVE JULY 1, 2005] **(a) IC 25-26-14, as amended by this act, applies:**

(1) after December 31, 2005, for an initial license issued under IC 25-26-14, as amended by this act; and

(2) on the first expiration date occurring after December 31, 2005, for renewal of a license issued under IC 25-26-14, before amendment by this act.

(b) The Indiana board of pharmacy established by IC 25-26-13-3 may establish an electronic pedigree pilot program to authenticate, track, and trace legend drugs. The pilot program must include participation of drug manufacturers, wholesale drug distributors, and pharmacies that are licensed in Indiana. The board may establish the requirements and guidelines for the pilot program.

(c) Before June 30, 2007, the Indiana board of pharmacy established by IC 25-26-13-3 shall conduct a study of the electronic pedigree pilot program. The study must include consultation with manufacturers, distributors, and pharmacies that participate in the electronic pedigree pilot program. The study may include consultation with manufacturers, distributors, and pharmacies that do not participate in the electronic pedigree pilot program. Based on the results of the study, the board shall determine a date to implement a mandatory electronic pedigree program. However, the board may not implement a mandatory electronic pedigree program until after:

(1) the board has completed the study under this subsection; and

(2) the board has consulted with the federal Food and Drug Administration concerning the implementation of a mandatory electronic pedigree program.

(d) The Indiana board of pharmacy established by IC 25-26-13-3 shall adopt rules under IC 25-26-14-8.5(7), as added by this act, prescribing the route that a legend drug travels that is in the normal distribution chain of custody.

(e) IC 25-26-14-26(b), as added by this act, applies only to offenses committed after December 31, 2005.

(f) This SECTION expires December 31, 2007.

SECTION 80. [EFFECTIVE JULY 1, 2005] **(a) Notwithstanding IC 25-35.6, as amended by this act, concerning issuance of a license, the health professions bureau shall issue a license in speech-language pathology as follows:**

(1) To each individual who applies for licensure and meets all

the following qualifications:

(A) Holds a license in speech and hearing therapy issued by the professional standards board.

(B) Has a master's degree in speech-language pathology or a related discipline.

(C) Has been employed as a speech-language pathologist for at least nine (9) months in the last five (5) years.

(2) To each individual who applies for licensure and meets all the following qualifications:

(A) Holds a life license in speech-language pathology issued by the professional standards board.

(B) Has:

(i) been employed as a speech-language pathologist for at least nine (9) months in the last five (5) years; or

(ii) taken at least thirty-six (36) hours of continuing education approved by the professional standards board or health professions bureau after December 31, 2001, and before January 1, 2007.

(b) This SECTION expires July 1, 2007.

SECTION 81. [EFFECTIVE JULY 1, 2005] **(a) Notwithstanding IC 25-35.6-1-8(b)(3), as added by this act, a speech-language pathologist is not required to hold a certificate of clinical competence in speech-language pathology or its equivalent issued by a nationally recognized association for speech-language and hearing to supervise speech-language pathology support personnel.**

(b) This SECTION expires July 1, 2010.

SECTION 82. [EFFECTIVE JULY 1, 2005] **(a) Notwithstanding IC 25-35.6-1-6(2), as added by this act, an applicant for an initial license as an audiologist is required to possess only a master's degree in audiology from an accredited educational program recognized by the speech-language pathology and audiology board.**

(b) This SECTION expires January 1, 2007.

(Reference is to EHB 1098 as reprinted April 6, 2005.)

Conference Committee Report
on
Engrossed House Bill 1098

Signed by:

_____	_____
Representative Messer Chairperson	Senator Dillon
_____	_____
Representative Brown C	Senator Simpson
House Conferees	**Senate Conferees**